VitaGuard® VG 310

Pulse oximeter

Operating instructions

getemed

Who should read which sections in these operating instructions?

The sections **3** to **7** colored blue at the top of the page and in the table of contents are intended specifically for caregivers without medical background knowledge.

The other sections are intended in particular for doctors and qualified medical staff.

1 General view and list of accessories

2 Intended use

3 Safety

4 Description

5 Steps before and after monitoring

6 Preparing for SpO_2 monitoring

7 Alarms, displays, and views during monitoring

8 Alarm and monitor settings

9 Information for the doctor and qualified medical staff

10 Algorithms and measuring principles

11 Evaluating stored data on a PC

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1 General view and list of accessories

The general view shows the monitoring system's most important components.

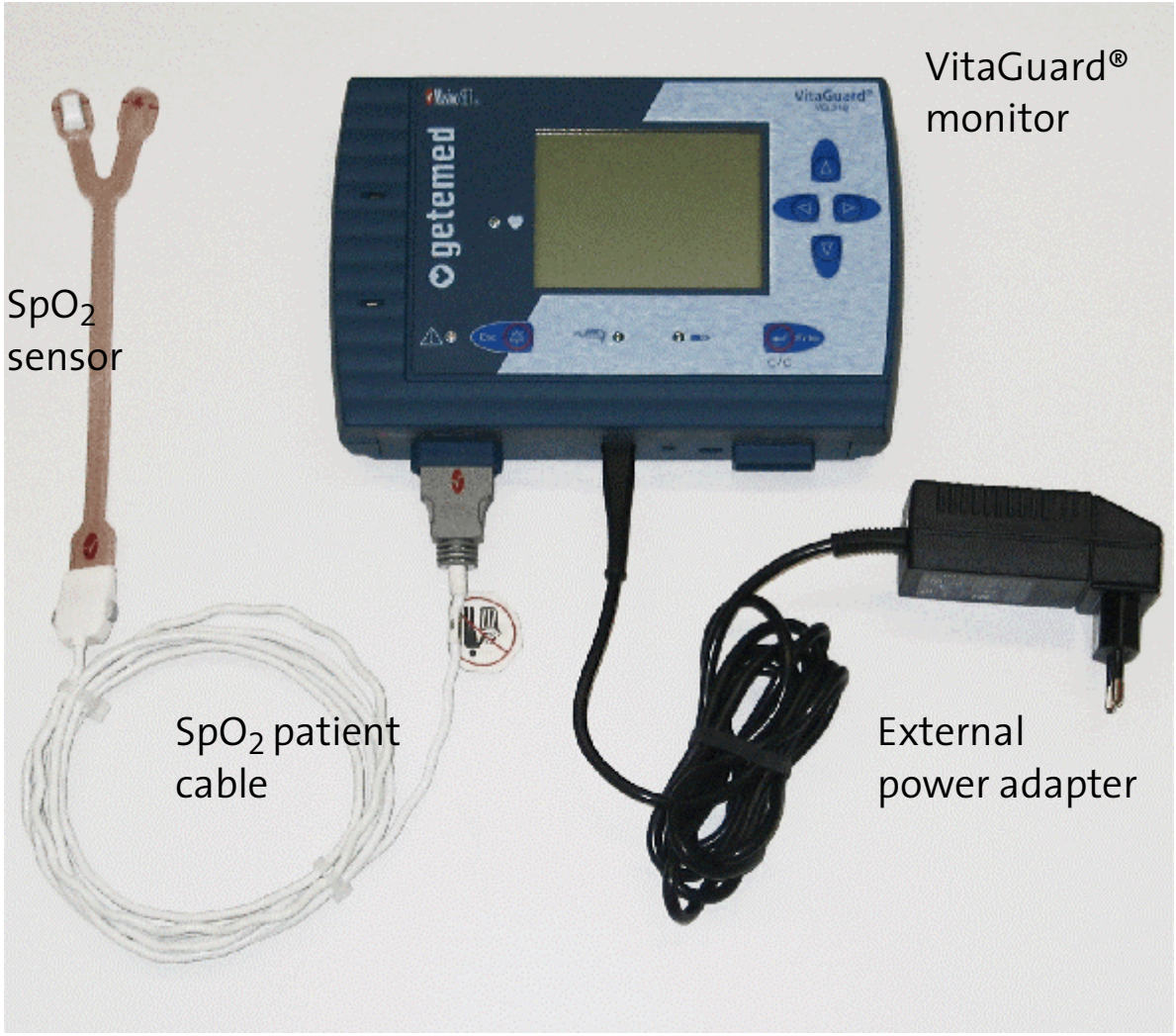


Fig. 1 General view of the monitoring system

The accessories listed in the following can be used together with VitaGuard® and can be ordered with the specified article numbers from getemed AG or authorized dealers. Please consult getemed AG or your authorized dealer for other approved accessories.

Product ..... **Article no. / REF**

VitaGuard® VG 310 Monitor (with Masimo SET®),
complete system 7311 3022

1 VitaGuard® VG 310 monitor

1 SpO_2 patient cable PC08

1 SpO_2 LNOP Neo sensor incl. spare adhesive strip

1 NA3000-2 external power adapter

1 rechargeable block battery

1 device bag

1 operating instructions, 1 quick reference

Transport case

NA 3000-2 external power adapter
(110 V–240 V~ / 50–60 Hz) 7344 1101

NAK 3000-2 automobile power supply adapter 7344 1201

Rechargeable block battery 7344 2201

Masimo SpO_2 patient cable PC08 (2.44 m) 70257

Masimo LNOP® NeoPt SpO_2 sensor (PU = 20 pcs)
(for one patient use only, infants < 1 kg) 70250

Masimo LNOP® Neo SpO_2 sensor (PU = 20 pcs)
(for one patient use only, infants < 10 kg) 70251

Masimo LNOP® Pdt SpO_2 sensor (PU = 20 pcs)
(for one patient use only, pediatric/ slender finger 10–50 kg) . 70252

Masimo LNOP® Adt SpO_2 sensor (PU = 20 pcs)
(for one patient use only, adult > 30 kg) 70253

Masimo LNOP® DCI reusable sensor (> 30 kg) 70254

Masimo LNOP® DCIP reusable sensor (10–50 kg) 70264

Other models are available in addition to the SpO_2 sensors listed here.

Operating instructions (English) 7381 3021
Alarm chart (English) 7383 1021

Device bag 7345 1001
VitaGuard® transport case (for the complete system) 7391 0001

AUX 01 RS232 cable for connecting VitaGuard®
to a serial PC port 7341 2002

AUX-02 modem cable for connecting a
modem to VitaGuard® 7341 3001

AUX-03 cable for connecting an external alarm unit
to VitaGuard® 7341 5001

AUX-04 cable for connecting VitaGuard®
to a nurse call system with 4 kV isolation 7341 5011

AUX-06 cable for connecting two external signal sources
to VitaGuard® 7341 6001

2 Intended use

This section provides information on the intended use of VitaGuard® and the limitations of this intended use.

The doctor treating the patient is responsible for the application of VitaGuard®. The specific “Information for the doctor and qualified medical staff” can be found on page 78.

getemed AG recommends qualified training for the caregivers in potentially necessary resuscitation techniques. Clearing the respiratory tract and the resuscitation of babies and infants require particular know-how that the treating doctor should communicate to the caregivers.

2.1 Label on the back of the device

The device label serves as a unique identifier for VitaGuard®. In addition, the label bears important cautionary information.

On the device label you will find the manufacturer’s name and address as well as the product and model name. The serial number of your device is given next to SN.

Hersteller:
getemed
Medizin- und Informationstechnik AG
Oderstraße 59 • 14513 Teltow • Deutschland
Produkt: VitaGuard®
Modell: VG 310
SN: 801 05 0452
CE 0197
2005
Hergestellt in Deutschland
• Schutzart durch Gehäuse: IP21
• Nicht in explosionsfähiger Atmosphäre einsetzen!
• Nur Netzadapter NA3000-2 verwenden!
• Nicht an abschaltbaren Steckdosen betreiben!
• Bei Batteriebetrieb nur neue, alkalische Batterien, Größe LR6, verwenden! Polarität beachten!
This device is covered under one or more of the following U.S.A. patents: 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,206,830; 6,157,850; 6,002,952 and international equivalents. U.S.A. and international patents pending.
NO IMPLIED LICENSE
Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.
VG310_DEU_Rev D

Fig. 2 Device label on the bottom of the device

2.2 Symbols and warnings

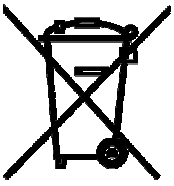
This symbol warns you that failure to observe these operating instructions can cause death or injury to the patient.

The book symbol means that you must not use the device when you are not familiar with the information contained in these operating instructions.

With this CE label and the CE approval number 0197 getemed AG confirms that VitaGuard® complies with all the pertinent regulations and in particular the requirements in Annex I of the Medical Devices Directive 93/42/EWG and that this has been approved by a notified body (TÜV Rheinland Product Safety).

This symbol means that the VitaGuard®'s SpO_2 socket is a type BF (body floating) application part that is protected against the effects of defibrillation.

The factory symbol shows the year of manufacture.



Like every electronic device, VitaGuard® and accessories contain metal and plastic parts that must be disposed of in such a way that they do not pollute the environment after their service live. For this reason, the device and accessories may be sent to getemed AG in an adequately stamped package, when possible in the original packaging, for free and proper disposal.

Note the warnings on the device label.

Do not use in explosive atmospheres!

Use the NA 3000-2 power adapter only!

Warning: Do not connect to an electrical socket controlled by a wall switch!

Only new alkaline batteries (LR6 or AA) must be used when the device is powered by non-rechargeable batteries! Note the polarity!

2.3 Indications

The SpO_2 and pulse rate monitor with the attached accessories is suitable for the permanent, non-invasive monitoring of arterial blood oxygen saturation (SpO_2) and of the pulse rate as measured with the SpO_2 sensor. The functional blood oxygen saturation displayed as $\%SpO_2$ is determined exclusively from the measurements of oxygenated and deoxygenated hemoglobin. The SpO_2 and pulse rate monitor is suitable for adult, pediatric, and infant patients, in mobile or stationary indoor and outdoor applications, including patients with weak blood flow and those in hospitals and other institutions.

2.4 Intended use and performance

The intended use of VitaGuard® is to monitor the pulse rate as well as the oxygen saturation. VitaGuard® is designed for applications at home and in rooms used for medical purposes. VitaGuard® has no therapeutic effect. VitaGuard® emits an acoustic and visual alarm when the measured pulse rate and/or oxygen saturation values violate the set alarm limits for a period set by the operator. The alarm limits can be set within particular values specified by VitaGuard®.

Blood oxygen saturation and pulse rate are monitored with an SpO_2 sensor suitable to the patient's age and weight. When the signal registered by the SpO_2 sensor is inadequate for the reliable measurement of values, a message appears on the display.

Physiological data measured for a set period before and after an alarm are stored and can afterwards be evaluated and documented.

VitaGuard® can be operated with the NA3000-2 power adapter (9 V), the NAK3000-2 automobile power adapter (e.g. in the cigarette lighter), four non-rechargeable batteries, or a rechargeable block battery. Non-rechargeable batteries or the rechargeable block battery serve above all to safeguard the monitor's functions during a power failure and to continue monitoring the heart rate and oxygen saturation when patients are in transit.

2.5 Limitations on VitaGuard®'s intended use

Even when operated in accordance with its intended use, VitaGuard® cannot detect all life-threatening situations under certain unfavorable conditions.

The monitoring of SpO_2 and pulse rate is adversely affected when the patient moves vigorously or is vigorously moved.

When the sensor is not attached correctly, ambient light can falsify measurements. One remedy is to cover the sensor with a dark or opaque material.

The monitor operates properly only when the SpO_2 sensor is correctly attached.

2.6 Information for the doctor on these operating instructions

In full knowledge of these operating instructions, the treating doctor must decide:

- whether the caregivers have to be trained in the performance of resuscitation measures,
- how the caregivers can be best prepared for monitoring and above all for the measures that must be taken in the event of an alarm,
- which view should be displayed

Information on SETTINGS PROTECTION that sets the display modes and user configurations can be found on page 72.

"Information for the doctor and qualified medical staff" is found on page 78.

3 Safety

The doctor decides whether the caregivers are able to use VitaGuard® for monitoring and whether they can implement appropriate measures in the event of an alarm.

3.1 Caregivers' tasks

With "caregivers" we mean those persons who are responsible during monitoring for the monitored patient's well-being, for example:

- parents or other members of the family,
- babysitters, when they too have been thoroughly prepared for the situation,
- nurses and other medically trained staff.

Observe in particular the information in those sections of the operating instructions that, like here, address you directly.

Observe the extensive safety instructions at the beginning of the section "Preparing for SpO_2 monitoring" on page 46.

VitaGuard® has no therapeutic effect. You may have to implement resuscitation measures in the event of an alarm.

The potential applications of VitaGuard® for high-risk patients are so many and diverse that we are unable to give any specific instructions on procedure in the event of an alarm. It is the doctor's task to inform high-risk patients and their caregivers in detail on the correct procedure in this case.

An alarm chart is available from getemed AG when monitoring children. This alarm chart presents a sequence of activities that are considered suitable by many medical specialists and pediatricians.

Never leave the patient's room without first making sure that the heart LED is flashing.

Make absolutely sure that you can react to an alarm within a few seconds. Move away from patients only so far that you can reach them within ten seconds.

Never modify settings without consulting the responsible doctor. Only the doctor knows the correct alarm limits and monitor configuration for each patient.

When you are not sure that VitaGuard® is in perfect operating order, check the patient's vital functions. Under no circumstances should you use VitaGuard® when you suspect a device defect.

In the event of ANY suspected VitaGuard® malfunction, continue to observe the patient until you can use a replacement monitor, or VitaGuard® has been examined by the doctor or authorized dealer.

Stop using VitaGuard® after the servicing interval of eighteen months has expired. Before the end of this period, make an appointment with your authorized dealer to check the safety and operability of your device.

Test the acoustic alarm unit every time you switch on VitaGuard®. This is explained in the section "Alarm test" on page 56.

Treat all leads and connections with particular care, and never use the connecting cables to lift VitaGuard®.

Switch off VitaGuard® before boarding an aircraft. When you want to transport VitaGuard® in your luggage, you should remove the batteries. This prevents other pieces of luggage from switching on the device by accident. An activated, but disconnected VitaGuard® will generate acoustic alarm signals.

3.2 Allergy risks to patients

Attach SpO_2 sensors to intact areas of skin only.

The use of SpO_2 sensors with adhesive materials may cause problems when the patient develops an allergy to adhesive tape or similar.

All materials that are used with VitaGuard® and can come into contact with patient or caregivers during normal operations are free of latex and are non-toxic in accordance with the standard ISO 10993-1.

3.3 Possible external interference to monitoring

Please bear in mind the possibility of other risks that are not listed here that can be caused by your specific monitoring environment.

3.3.1 Installation and environment

We recommend hanging VitaGuard® in the delivered bag at a place where the display can be easily viewed.

Check, as described in the section “Alarm test” on page 56, that you can hear alarms and where you can hear them. Think also of the activities that cause noises, for example showering or vacuuming. Think before you raise the volume of your television or stereo. Also, the VitaGuard®’s alarm outlet should not be obstructed by any objects that absorb sound.

Never place VitaGuard® or the power adapter such that they could fall on the patient. For example, the power adapter could become detached from an overhead socket when the cable is pulled.

Do not immerse either VitaGuard® or the accessories in liquids.

Variations in temperature and air humidity could lead to condensation forming in and on VitaGuard®. Wait for at least two hours after VitaGuard® has visibly dried on the outside before using it for monitoring.

Do not operate VitaGuard® in environments containing explosive gases, flammable substances, nitrous gases, or highly oxygen-enriched atmospheres. Do not use VitaGuard® at extreme temperatures below 5 °C or above 40 °C. Do not place VitaGuard® near heat sources such as radiators, ovens, etc. Do not expose it to direct sunlight.

Always lay all cables and in particular any extension cables so that nobody can trip over them.

Do not place VitaGuard® directly next to the patient's head: risk of hearing damage!

3.3.2 Noise risks to monitoring

When the alarm cannot be set to a volume that is sufficiently above the prevailing ambient noise levels, you must keep VitaGuard® and its display within view. The visual signals from the alarm LED and display must then be relied upon to recognize critical situations.

You can also use the external alarm unit available from getemed AG that raises the volume of the alarm signals from VitaGuard®.

Information on the alarm signal types and volumes can be found in "Alarms, displays, and views during monitoring" on page 56. The alarm pitch is set as explained in the section "SYSTEM menu – general settings" on page 70.

3.3.3 Electrostatic interference

Electrostatic build-up that, for example, a person can pick up on certain carpets must not discharge through the VitaGuard® connector sockets.

For this reason, avoid touching the electrically conducting parts, or discharge any electrostatic build-up beforehand by, for example, touching an earthed water pipe or heater.

3.3.4 Electromagnetic interference

VitaGuard® is not designed for applications near strong electromagnetic fields. These interference fields are frequently emitted by devices with large electric power consumptions. Keep a good dis-

tance from e.g. washing machines, computers, microwaves, vacuum cleaners, power tools, etc.

The device and the system can be used in the home and in all other environments that public utilities supply directly.

Bear in mind that portable and mobile HF communication devices, e.g. cellular phones, radio equipment, walkie-talkies, etc., can interfere with the monitor and influence its operability.

Bear in mind that non-approved accessories can amplify emitted interference and reduce the device's immunity.
Do not place the monitor directly next to other electrical equipment, and do not stack monitors on top of each other.

When the monitor has to be placed next to or on other equipment, check that the monitor operates as designed in this environment.
We recommend you to check at regular intervals:

– that the displayed signals are not disrupted when the patient is not moving,
– whether the same technical alarm messages are repeatedly displayed.

When you discover disruptions:
– if possible, switch off the interfering equipment or move this equipment to another site.

VitaGuard® uses high-frequency signals exclusively for its internal functions. As a result, its emitted interference is very low, and disruption to neighboring electronic equipment is unlikely.

False diagnoses are possible when monitored values are corrupted by interference from electric or electromagnetic fields and this escapes the doctor's attention. Every time you analyze stored data, consider the possibility of interference from electric or electromagnetic fields.

VitaGuard®'s emitted interference and immunity to external interference are within the limits for life-supporting systems stipulated in the standard EN 60601-1-2.

3.4 Safety with approved accessories only

Use VitaGuard® only with the delivered or approved accessories and in accordance with the information contained in these and the accessories' operating instructions.

SpO_2 sensors, cables, and power adapters can be ordered from your authorized dealer or directly from getemed AG. The telephone number of your authorized dealer was given to you during your training on how to operate the device, or it is found on a label your authorized dealer has attached to VitaGuard®.

Bear in mind that monitoring can continue without interruption only as long as the required consumables are available. In emergencies of this nature you can call your authorized dealer, who provides 24-hour emergency services. Please try, however, to avoid unnecessary stress for both yourself and your authorized dealer, and order your consumables in good time.

The modem used to transfer monitoring data must comply with the requirements under the German and European standard DIN EN 60950 "Safety of IT Equipment" with the amendments A1–A4. These details are found in the modem's operating instructions.

3.5 Handling patient cables

Always lay patient cables at a good distance from the patient's head and neck. Lay each patient cable inside the clothing, and secure it in place in such a way that no harm can come to the patient or cable (strangulation, twisting).

Make sure when laying and securing patient cables that these cannot kink (kinking causes damage).

For hygiene reasons, always use the same patient cable on the one patient. Disinfect patient cables before using them on a new patient.

When more than one monitor is used in the one environment, each monitor should always be connected to the same patient cables and the same power adapter. Faults can therefore be located and remedied faster.

3.6 Power supply reliability

Before first using VitaGuard® for monitoring, familiarize yourself with the section “Power supply” on page 31. Monitoring is safe-guarded only when the power supply is in perfect operating order.

CAUTION: Danger of electric shock! Never open the external power adapter or the connecting cable.

Exclusively the NA 3000-2 approved for VitaGuard® must be used as the external power adapter.

VitaGuard® is usually delivered with the external power adapter for European supply networks. For other supply networks, use only the plug adapters available from getemed AG.

Do not use the external power adapter in sockets that can be switched off or dimmed.

When the VitaGuard® external power adapter is plugged into a multiple socket outlet, only the modem may be connected to this outlet simultaneously.

When an extension cable is used with a multiple socket outlet, this outlet must not lie on the floor. Otherwise water may penetrate the outlet and damage the monitor.

The external power adapter and the power outlet must be free of damage.

Never use the external power adapter’s cable to lift VitaGuard®.

Stop using the external power adapter when it has fallen or been dropped.

Do not operate the external power adapter in a damp environment (e.g. in the bathroom).

Always leave the batteries in VitaGuard®, even when this is operated through the external power adapter.

VitaGuard® operates with batteries: either non-rechargeable batteries or a rechargeable block battery. VitaGuard® must be operated only with the rechargeable block battery available from getemed AG or new alkaline non-rechargeable 1.5 V batteries (LR6 or AA), e.g. VARTA UNIVERSAL ALKALINE. Bear in mind that cheaper non-alkaline non-rechargeable batteries can have a considerably reduced operating lifetime, in some cases only 10–15% of the brand name batteries we recommend.

Do not under any circumstances use single rechargeable batteries available on the market.

Never use a non-rechargeable battery and a rechargeable battery together in the device, and never mix old and new batteries.

To prevent leaking batteries from damaging health and property, remove non-rechargeable batteries from VitaGuard® when it is not used for longer than a week. Information on “Replacing batteries” can be found on page 33.

3.6.1 Battery voltage indicator

When VitaGuard® is powered only by non-rechargeable batteries, check the battery voltage indicator on the display every hour. At least one quarter of the battery symbol must be black.

Fig. 3 Battery voltage indicator

When VitaGuard® is powered from the supply network and commercially available non-rechargeable batteries are inserted, check the battery voltage indicator on the display every day. Even when the device is powered from the supply network, you must replace

the non-rechargeable batteries as soon as one quarter of the battery symbol on the display is black.

If necessary, a display message will prompt you to insert new non-rechargeable batteries or to recharge the block battery.

3.6.2 Interruptions to the power supply

When the external power adapter is connected VitaGuard® operates automatically in supply network mode. When the supply network fails, VitaGuard® switches automatically to battery mode – when batteries are inserted.

As long as VitaGuard® is powered from the external power adapter or the automobile power supply, the green LED next to the power adapter symbol lights up.

Normal voltage fluctuations in the supply network do not adversely affect monitoring with VitaGuard®. Following a power supply failure, the current alarm settings are retained for at least thirty days and are again available when the device is switched back on.

3.6.3 Using the rechargeable block battery

Note the warnings on the rechargeable block battery's label.

Do not open or short-circuit!

Do not throw into a fire!

Avoid temperatures over 50 °C!

The charging time for the block battery is at most six hours.

Fig. 4 Rechargeable block battery

Also note the recycling symbol on the label. This means that the block battery must be recycled when its service life has expired.

Do not expose the block battery to direct sunlight. For example, temperatures greater than 50 °C can easily occur on a vehicle's dashboard or rear shelf.

When you intend to use VitaGuard® powered from the rechargeable battery block and disconnected from the supply network, you must first make sure that the block battery is fully charged. For this reason, check the "Battery charging" LED. The battery is being charged as long as this LED light is continuously on. When the LED flashes every second, the battery is full and compensation charging is activated.

Sometimes the light will go out for a short time in the interval between battery and compensation charging.

3.7 Safety with proper maintenance only

VitaGuard® can operate safely and reliably over the long term only when it is subject to proper maintenance and use.

Check visually for any damage on VitaGuard®, the patient cables including the connections, the external power adapter, and the SpO_2 sensor every time you use VitaGuard® for monitoring.

Every eighteen months at the latest VitaGuard® and accessories must be serviced by getemed AG to comply with safety regulations.

Repairs must be performed by getemed AG only. Clarify the necessary procedure with your authorized dealer.

For the protection of our service personnel, disinfect VitaGuard® and the patient cables with Virkon®, available as a spray or wiping solution, before sending them to getemed AG.

3.7.1 Cleaning VitaGuard® and accessories

Before cleaning VitaGuard®, remove the batteries.

Before cleaning VitaGuard®, detach the cables from the monitor and from the patient.

Do not under any circumstances use solvents like ether, acetone, or benzene. These substances can cause malfunctions and attack the housing plastic.

Also, do not use any cleaning agents containing abrasive substances and no coarse brushes or hard objects.

VitaGuard® and accessories can be cleaned any number of times when the recommended cleaning agents are used.

VitaGuard® and accessories must not be sterilized.

VitaGuard® and the cable plugs must not be immersed or otherwise penetrated by liquid.

Cleaning the exterior is best done with a non-linting cloth moistened slightly with water or a mild soap solution.

getemed AG recommends disinfecting the device with Virkon®, available as a spray or wiping solution.

Patient cables can be cleaned with liquid Cable Care or with a 70% alcohol solution. Baby oil has proved to be effective in removing residue from adhesive strips.

The VitaGuard® bag can be washed by hand at 30 C. It must not be put in the laundry dryer.

3.7.2 Checking and cleaning the battery terminals

Check the battery compartment every month for traces of leaking and for deposits on the battery terminals indicating leaks. Contact your authorized dealer and clarify further procedures when a battery starts to leak.

The battery compartment and how to replace the batteries are explained in the section “Replacing batteries” on page 33.

3.8 Disposing of non-rechargeable batteries, the device, and accessories

getemed AG takes back all of the parts it delivers. For hygiene reasons these parts do not extend to consumables like sensors that have been in direct contact with the patient.

The symbol of the crossed-out waste container on the battery packaging is to remind you that under no circumstances must you dispose of batteries in normal household waste. As the end consumer you are legally obliged to return used batteries or dispose of them properly. You can return used batteries to us.

Place consumables like sensors in a plastic bag before disposing of them in household waste.

Please do NOT send us ANY used sensors.

4 Description

We recommend placing VitaGuard® in the bag provided. This bag protects the monitor and can be hung from a site where it cannot fall.

Fig. 5 VitaGuard® and bag with power and patient cables

4.1 Power supply

VitaGuard® is usually delivered with the power adapter for European supply networks. For other supply networks, contact getemed for the appropriate plug adapter. Observe the information in “Power supply reliability” on page 24.

Fig. 6 Power adapter socket

VitaGuard® is normally supplied by the power adapter (Fig. 7, left) in the 230 V/ 50 Hz supply network.

The NAK3000-2 automobile power supply adapter (Fig. 7, right) for vehicle dashboards can be inserted in this socket.

Fig. 7 Power adapter for 230 V/ 50 Hz supply network and automobile power supply

When VitaGuard® is supplied by the external power adapter, the green LED lights up next to the power adapter symbol. In addition, the display backlight is activated when VitaGuard® is switched on.

When VitaGuard® is supplied by the power adapter only, without inserted batteries, a display message will prompt you to insert batteries.

When VitaGuard® is supplied by the power adapter, charging of the inserted rechargeable block battery is activated. The LED next to the battery symbol illuminates.

4.1.1 Power failure with inserted batteries

VitaGuard® automatically switches to battery mode when the external power supply fails or the power adapter is disconnected. In this event a technical alarm is permanently emitted until the power supply has been reinstated or the <Esc> key pressed.

When the supply network LED is off, but you can still see the usual monitor displays, VitaGuard® is being supplied by the batteries.

4.1.2 Power failure without batteries

VitaGuard® is fitted with an internal battery. This provides the voltage for an acoustic signal that is emitted when monitoring cannot be continued during a power failure.

The acoustic alarm from the internal battery does not stop until VitaGuard® has been switched back on after the power adapter has been reconnected or batteries have been inserted.

A power failure jeopardizes monitoring when

- the batteries in the VitaGuard® are nearly depleted or
- no batteries have been inserted and VitaGuard® is disconnected from the external power adapter.

To stop the power draw on the internal battery, it is important that non-rechargeable batteries are inserted as quickly as possible or, better, the power adapter is reconnected.

> **VitaGuard® must not be used for monitoring when the internal battery is depleted. This status appears on the display.**

A new internal battery can be installed at getemed AG only, so you must continue monitoring with a replacement device until the internal battery has been displaced.

4.1.3 Replacing batteries

Switch off VitaGuard® before replacing batteries.

Push back the catch and lift off the battery cover to open the battery compartment. Insert either four non-rechargeable batteries or the rechargeable block battery.

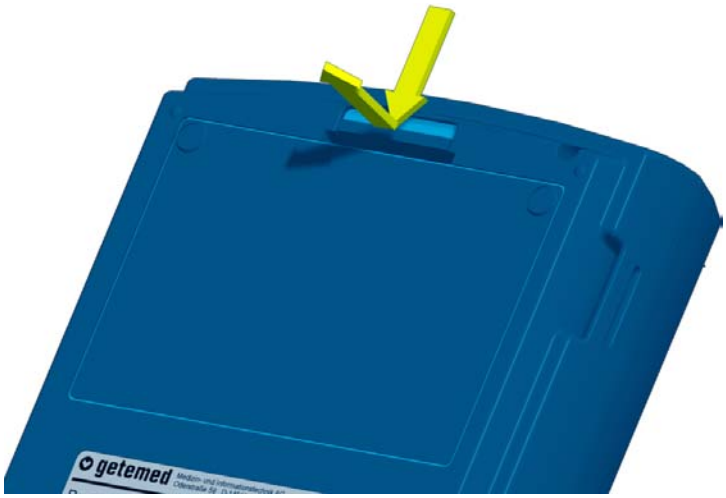


Fig. 8 Opening the battery compartment

Make sure that the + symbols on the batteries and in the compartment match before inserting non-rechargeable batteries.

Fig. 9 Opened battery compartment and polarity

Observe the following instructions when you use the rechargeable block battery.

- Never use force to insert the block battery.
- The bottom of the block battery has a guide groove that prevents the battery from being inserted the wrong way. Make sure when inserting the block battery that the labeled side is on the top and the metal terminals point to the device label.

- You will feel a slight pressure from the terminal spring connections when inserting the block battery.

Fig. 10 The arrows show how the block battery is correctly inserted.

4.1.4 Using the automobile power supply adapter

Use only the NAK 3000-2 automobile power supply adapter to operate VitaGuard® from a vehicle's dashboard.

Do not leave the automobile power supply adapter overnight in the vehicle (particularly during the cold season). Otherwise condensation may form on and in the device.

The NAK 3000-2 automobile power supply adapter is connected to the VitaGuard® power adapter socket. NAK 3000-2 features a universal safety plug (DIN ISO 4165) for the dashboard lighter. Automobile power supply mode is indicated on VitaGuard® by the green LED beside the power adapter symbol.

The specifications of the automobile power supply adapter are as follows:

Input ..... Automobile voltage supply at 12–24 V
Output ..... 9 Vdc
Max current ..... < 500 mA
Operating temperature ..... +5 to +50 °C
Connection to VitaGuard® ..... 3-pin plug
Connection to automobile supply .... Universal safety plug (DIN ISO 4165)
Connecting cable length ..... 2 m ± 20 cm

4.2 VitaGuard® connections

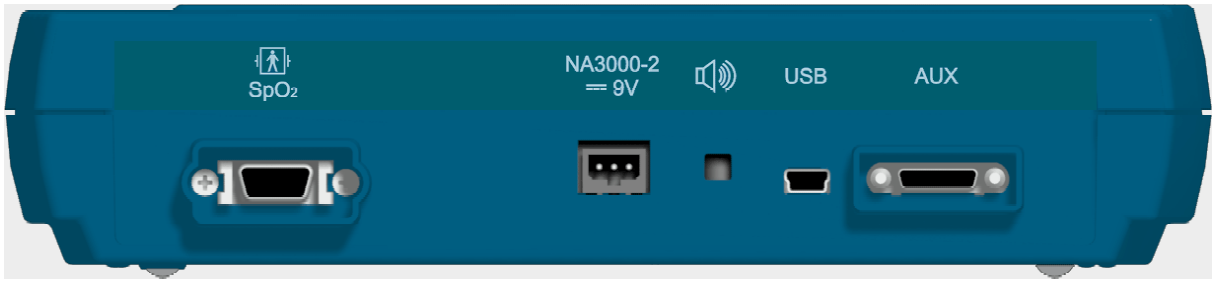


Fig. 11 Overview of VitaGuard® connections

For safety reasons, only those accessories that getemed AG has delivered or approved must be connected to VitaGuard®.

Hold VitaGuard® firmly with one hand when connecting and disconnecting plugs.

Never use force when connecting and disconnecting cables. Always insert and remove the plugs parallel to the sockets to prevent damage to the sensitive contacts.

Only the doctor, in full knowledge of the information under “Connections to the USB and AUX ports” on page 79, must decide which devices are connected to the USB and AUX ports.

4.2.1 Patient cable for SpO_2 sensors

Fig. 12 SpO_2 socket

The patient cable for the SpO_2 sensors is connected to the SpO_2 socket.

4.2.2 Power adapter

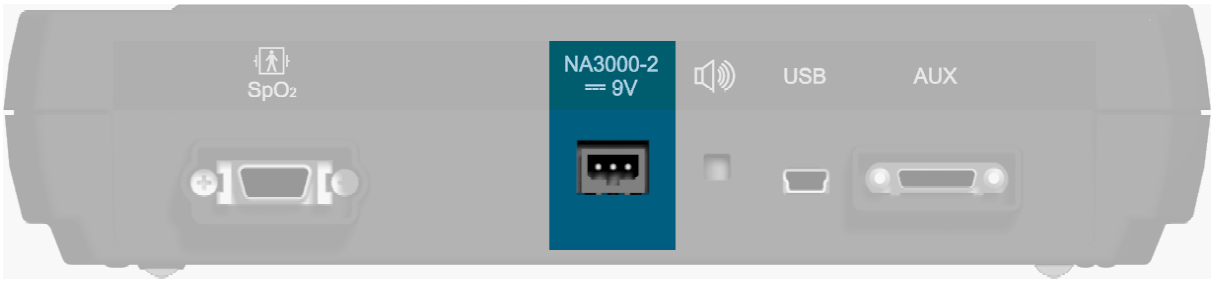


Fig. 13 Power adapter socket

The external power adapter socket is for connecting the NA 3000-2 external power adapter or the NAK 3000-2 automobile power supply adapter.

4.2.3 Sound outlet (no socket)

Fig. 14 Sound aperture

The outlet in the figure is not a socket, but a sound hole for the internal system monitor buzzer.

This outlet emits a pulsating sound when the external power adapter is disconnected from the monitor and no batteries are inserted.

The sound outlet is located between the cable sockets so that it cannot be covered by objects such as cushions or curtains.

4.2.4 USB port

Fig. 15 USB port

The USB (universal serial bus) port serves to read out stored data and to modify the VitaGuard® settings via a PC.

4.2.5 AUX port

Fig. 16 AUX port

The AUX (auxiliary) port can take the following connections:

- Two analog inputs
- Modem for communicating data
- Nurse call unit
- External alarm unit

VitaGuard® cannot confirm whether an alarm signal has been reported by a nurse call unit. As explained in the section “Alarm test” on page 56, check each time you switch on the device that an alarm signal is really transferred and the alarm reported.

Measure the time it takes for an alarm to be reported and the time needed to reach the patient. No more than ten seconds must pass between these times. Observe the operating instructions for the nurse call unit.

4.3 Membrane key panel

Do not apply excess pressure to the keys.

VitaGuard® recognizes key presses only when the keys have been pressed for about one second.

There are six membrane keys on the top side of VitaGuard®.

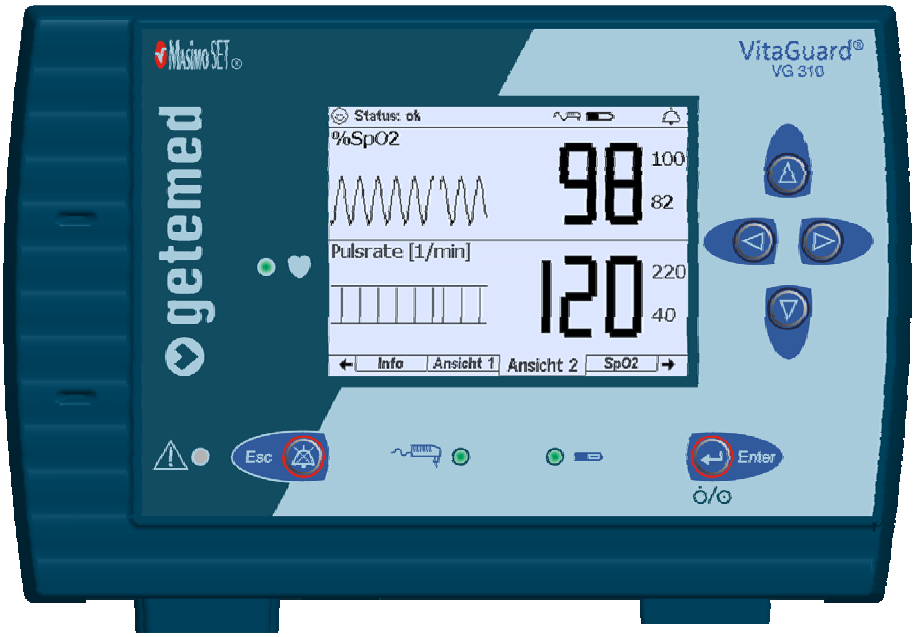


Fig. 17 Keys on the top side

4.3.1 Direction keys

With the direction keys you navigate from one window to the next.

The direction keys also allow you to navigate within the menu structure.

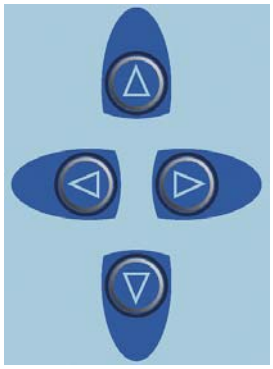


Fig. 18 Direction keys

4.3.2 <Enter> key

- The <Enter> key switches VitaGuard® on and off.
- The <Enter> key also lets you confirm changes to the monitor settings.

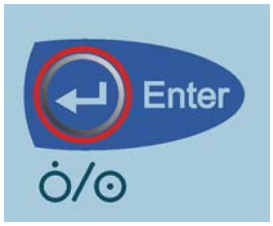


Fig. 19 <Enter> key

4.3.3 <Esc> key

- When an alarm is triggered, the <Esc> key serves to deactivate the acoustic alarm signal for a set alarm mute time. During an alarm condition the red alarm LED and the violated alarm limit flash. The acoustic alarm is again emitted if the alarm condition persists after the alarm mute time has expired. Pressing the <Esc> key during the alarm mute time a second time reactivates the acoustic alarm.

Fig. 20 <Esc> key

- Also when an alarm has automatically ended (because the vital functions have restabilized by themselves) the alarm LED and the violated alarm limit continue to flash until you press the <Esc> key. The alarm LED, however, flashes slower than during an alarm.

- The <Esc> key cancels unsaved changes to the monitor settings or moves back to the next-higher menu.

4.4 Color LEDs (Light Emitting Diodes)

When VitaGuard® is switched on, all LEDs light up for a short time so that you can see they work properly. During this time, the alarm LED first lights up red and then yellow.

4.4.1 Alarm LED

- In the event of a higher-priority alarm, i.e. a physiological alarm, the alarm LED flashes red.
- In the event of a medium-priority alarm, i.e. a technical alarm, the alarm LED flashes yellow.

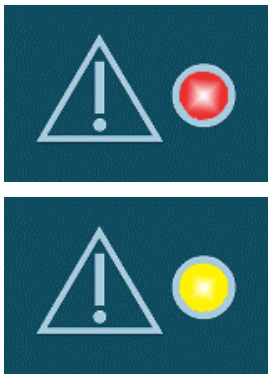


Fig. 21 Alarm LED

4.4.2 Heart LED

The LED with the heart symbol flashes with every pulse of the patient. In other words, this LED flashes as fast as the heart beats.

Fig. 22 Heart LED

The flashing green LED shows you even in complete darkness that monitoring is activated.

Also, the SYSTEM menu lets you switch on and off an acoustic signal that is emitted synchronously with the pulse.

4.4.3 Power supply and battery LEDs

- When the LED with the power adapter symbol lights up, VitaGuard® is being powered from the supply network or an automobile power supply.

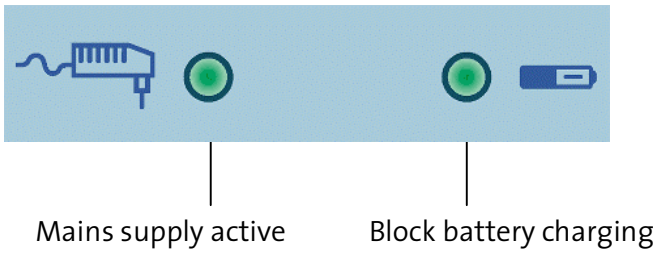


Fig. 23 Power supply LEDs

- When the LED with the power adapter symbol does not light up, but the usual monitor displays are visible, VitaGuard® is being supplied by batteries (four non-rechargeable batteries or the rechargeable block battery).

The light from the LED with the battery symbol is permanently on when the block battery is being charged in VitaGuard®. A depleted block battery takes up to six hours to recharge.

When the block battery is fully charged the LED with the battery symbol flashes every second to indicate that compensation charging is active. The block battery must therefore be fully charged at all times in the event that the power supply from the external power adapter fails.

4.5 The display

Each of the “Alarms, displays, and views during monitoring” are explained on page 56. Pressing the ◁ key in VIEW 1 takes you to the INFO screen with the current information for the doctor. Pressing it again takes you to the SYSTEM menu for the basic VitaGuard® settings.

After the monitor is switched on it can take up to twenty seconds before the first values are displayed.

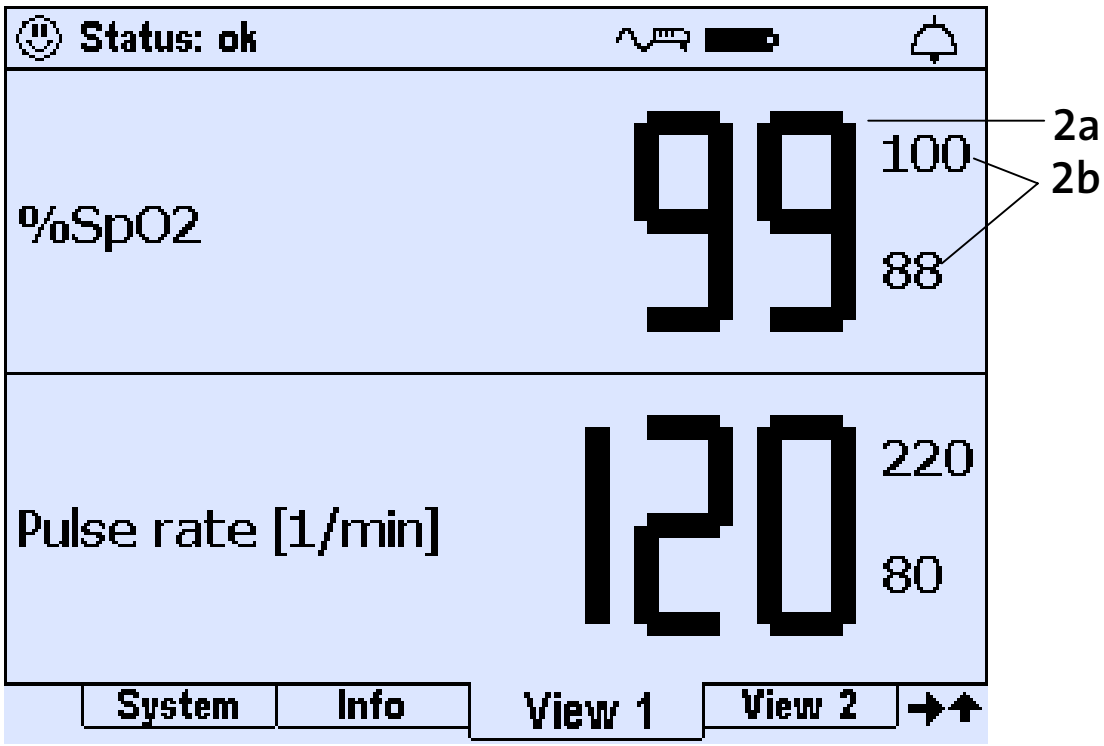


Fig. 24 Current values and alarm limits in View 1

1 The status line at the top of the display shows messages (on the left) and symbols (on the right) for the external power supply and alarm activation.

2 For both vital functions, as here SpO_2 **[2]**, the current value for each vital function **[2a]** is shown in large digits. Smaller digits to the right show the set alarm limits **[2b]**.

5 Steps before and after monitoring

The following summary shows you all the necessary measures that need to be taken before monitoring. Also read information on how VitaGuard® is switched on and off.

The doctor and the qualified medical staff are responsible for all other important activities when “Preparing for a new patient” (see page 78).

5.1 Summary of steps before monitoring

- Insert the battery or batteries (do not switch on yet!).
- Use the external power adapter to connect VitaGuard® to the supply network (do not switch on yet!).
- Attach the SpO_2 sensor to the patient.
- Connect the SpO_2 patient cable to VitaGuard®.
- Connect the SpO_2 sensor to the patient cable.
- Switch on VitaGuard® as explained in the next section.
- Make sure that after the monitor is switched on the indicator lamps light up briefly and a short sound is emitted by the alarm buzzers.
- Check that the alarm limits displayed are the same as those recommended by the doctor.

5.2 Switching on

Press the <Enter> key for several seconds to switch on VitaGuard®.

In the first minute of operation no acoustic signals are emitted so that you have time to check all cables. The alarm bell is crossed out

for this time and the remaining time is shown next to it. Text messages, on the other hand, are shown from the beginning.

When no patient cable is connected, an acoustic reminder signal is emitted as a short tone every twenty seconds after the monitor is switched on. The technical alarm for cable monitoring is not activated until the patient cable is connected and the first plausible data have been calculated. A text message in the status line reports from the beginning that the cables are being checked.

After the device has been switched on, the following displays and signals show you that the monitoring system is fully operable.

- All indicator LEDs light up briefly. During this time the alarm LED first lights up red and then yellow.
- A brief tone is emitted to indicate that the acoustic alarm buzzer is fully operable.

If the alarm buzzer does not emit the acoustic signal after the device has been switched on, you must immediately send VitaGuard® to getemed AG or your authorized dealer for inspection. Please consult your authorized dealer for a replacement device.

Observe the patient carefully until the replacement device arrives. Bear in mind that the patient is not being monitored at this time and that no alarm will be reported in an emergency.

5.3 Switching off

Always switch off VitaGuard® in the manner described here.

1 Press the <Enter> key and keep this pressed: the message PRESS Esc KEY appears.

2 Briefly press the <Esc> key, still keeping the <Enter> key pressed, and then release both keys.

The switch off command is acknowledged by two short beeps.

Data must be stored before the device finally switches off. For this reason, VitaGuard® needs about another two seconds after the keys are released until it switches off completely.

5.4 Summary of steps after monitoring

- Switch off VitaGuard® as explained in the previous section.
- Detach the SpO_2 sensor, carefully removing the adhesive strip from the skin.

If the procedure concerning stored data has not been clarified during your training, then please contact your doctor.

6 Preparing for SpO_2 monitoring

The information in this section refers primarily to the use of adhesive strip sensors. Also available, however, are SpO_2 sensors that can be disinfected and reused (permanent sensors) for brief examinations and for monitoring patients with allergies.

- LNOP® Neo will be explained as an example SpO_2 sensor for children.
- LNOP® Adt will be explained as an example SpO_2 sensor for adults.

Preparing for SpO_2 monitoring involves:

- attaching the sensors to the patient
- laying and securing the patient cable
- connecting the SpO_2 patient cable to VitaGuard®

6.1 Safety instructions for SpO_2 monitoring

For hygiene reasons, check that there is no damage to the sensor's packaging before opening it. Use adhesive strip sensors on the one patient only.

Remove the adhesive sensors no later than every eight hours and permanent sensors no later than every four hours so that you can inspect and, if necessary, clean the attachment sites on the patient's skin.

When the blood flow or attachment site is not satisfactory, attach the sensor to a different site, and inspect this site more often.

Be particularly careful with patients exhibiting weak blood flow: failing to check the sensors frequently may lead to skin damage and pressure-induced necrosis. Check no later than every two hours in these cases.

Connect the SpO_2 sensors only to the corresponding patient cable and this only to the corresponding socket on VitaGuard®.

Do not use adhesive strip SpO_2 sensors on patients exhibiting allergic reactions to adhesive strips or similar.

Securing sensors incorrectly, e.g. too tightly, can damage tissue.

Do not use damaged sensors. Replace sensors immediately if they exhibit any damage.

Do not immerse the sensors in liquids and do not attempt to sterilize them.

An improperly attached sensor can falsify measurements.

Do not attach the SpO_2 sensor to a limb that has or will have a catheter or pressure cuff during monitoring.

Secure the sensors and cables so that they cannot harm, strangle, or be swallowed by the patient. Always lay the patient cable at a safe distance from the patient's head and neck. Lay the patient cable when monitoring small children inside their clothing so that it exits at the foot. On larger children and adults you can, for example, lay the patient cable so that it exits between the trousers and pullover.

To prevent damage, avoid all kinks, folds, and any other unnecessary bends in the sensor cable.

6.2 Operation of SpO_2 sensors

SpO_2 sensors consist of a transmitter diode (referred to as "transmitter" in the following) and a receiver. The transmitter is identified by the red star symbol on the adhesive strip. The receiver is identified by its round window and the white plastic part on the adhesive strip behind it.

The transmitter emits light, the receiver detects this light. When this light penetrates arterial blood vessels, the composition and intensity of the light picked up by the receiver change.

The SpO_2 monitor can calculate the percentage level of blood oxygenation from the composition of the light picked up by the receiver. However, it is important that no other light, whether daylight or ambient light, can reach the receiver. More detailed explanations can be found in the section “Measuring principle for the SpO_2 monitor” on page 103.

6.3 SpO_2 sensor adapted to the patient’s size and weight

The following lists a number of SpO_2 sensors that are also available.

- The LNOP® Neo delivered with VitaGuard® is an adhesive strip sensor for measuring the functional arterial blood oxygen saturation (SpO_2) of infants weighing up to 10 kg.
- Sensors of the type LNOP® NeoPt are available for monitoring premature infants with sensitive skin.
- The sensor LNOP® Pdt can be used on children weighing between 10 and 50 kg.
- The sensor LNOP® Adt is suitable for patients over 30 kg.

Information on other sensors can be obtained from getemed AG or your authorized dealer.

6.4 Choosing the sensor site

- Always choose a site that is intact, has good blood flow, and covers completely the receiver window. Information on choosing the right attachment site can be found on the sensor’s packaging.
- Choose a site such that the sensor’s transmitter and receiver can lie exactly opposite each other.
- The distance between the transmitter and the receiver should not be greater than two centimeters.

- On infants with thick or swollen feet, the big toe is often better than the whole foot.
- Clean and dry the attachment site.
- Choose a site where the sensor and patient cable can least restrict the patient's freedom of movement.

6.5 Repositioning or replacing the sensor

Sensors used for a long time do not adhere as well as new ones.

When VitaGuard® does not display plausible values for the pulse rate and oxygen saturation, the sensor may not be attached to the optimal site or may not be properly secured.

- Check the sensor's position, and if necessary, move the sensor to a different site.
- Always replace a sensor when the displayed pulse rate and the displayed percentage level of oxygen saturation remain unconvincing despite the sensor's new site.

6.6 Reasons for unconvincing SpO_2 values

Clarify with the doctor whether one of the following situations may have arisen:

- the sensor is improperly secured or used (e.g. when the transmitter and receiver do not lie exactly opposite each other),
- the patient moves vigorously,
- the sensor picks up bright ambient light, e.g. from powerful lamps, IR heater lamps, direct sunlight, etc.,
- venous pulsation,
- a catheter or pressure cuff has been applied to the same limb as the sensor,

- the blood exhibits appreciable quantities of dysfunctional hemoglobin, e.g. carboxyhemoglobin or methemoglobin,
- blood dyes have been used such as indocyanine green, methylene blue, or other substances that contain coloring agents and therefore affect the blood color.

6.7 Why the pulse rate is not displayed

Clarify with the doctor whether one of the following situations may have arisen:

- The sensor is secured too tightly (dangerous for the patient),
- Bright ambient light,
- Inflated blood pressure cuff on the same limb as the sensor,
- Arterial occlusion near the sensor,
- Low blood pressure, serious vasoconstriction, anemia, hypothermia, cardiac arrest, or shock.

6.8 Attaching the SpO_2 sensor to an infant's foot

Note that the SpO_2 sensor type LNOP® Neo for infants is described here as an example. The doctor must decide which SpO_2 sensor type to use in each case.

LNOP® Neo is an SpO_2 sensor for use with one patient only weighing less than 10 kg.

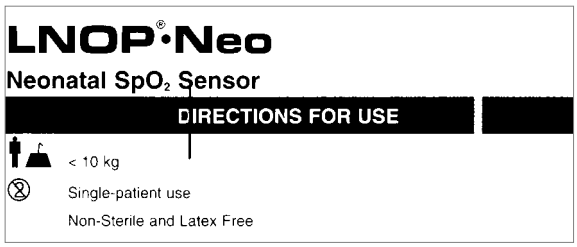


Fig. 25 Label on the LNOP® Neo SpO_2 sensor

LNOP® Neo is free of latex, is not sterile, and cannot be sterilized.

The foot is the preferred attachment site on newborns. Alternative sites are also the palms and backs of the hands.

On infants weighing between 3 and 10 kg with thick or swollen feet, the LNOP® Neo sensor can be secured to the big toe. In this case, the following information for the sensor's receiver does not refer to the sole of the foot, but to the underside of the big toe. An alternative attachment site is also the thumb.

1 Open the packaging and remove the sensor. Hold the sensor at the stem of the Y and remove the protective cover from both the sensor and the adhesive strip. Align the end of the sensor so that the contacts point away from the patient. Align the receiver along the fourth toe and press it against the sole of the foot (Fig. 26).

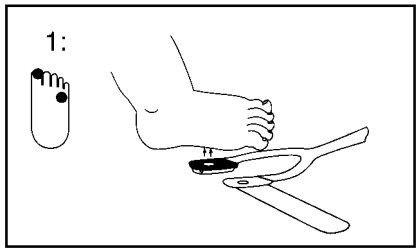


Fig. 26 Positioning the sensor

2 Align the transmitter window along the top of the foot directly opposite the receiver. Wrap the adhesive strip around the foot to secure the transmitter and receiver (Fig. 27). Check and if necessary correct the positions.

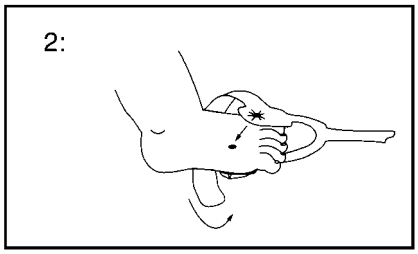


Fig. 27 Aligning the sensor and receiver

3 The opening in the receiver window must be completely covered by the foot (Fig. 28).

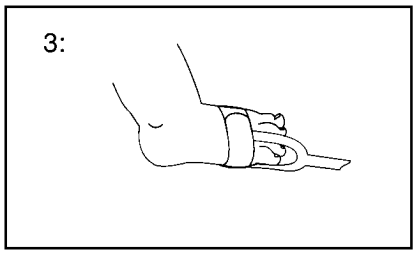


Fig. 28 Correctly attached LNOP® Neo sensor

6.9 Attaching the SpO_2 sensor to an adult's finger

Note that the SpO_2 sensor type LNOP® Adt for adults is described here as an example. The doctor must decide which SpO_2 sensor type to use in each case.

The LNOP® Adt sensor designed for adults weighing over 30 kg is identified by the label illustrated on the right.

Fig. 29 Label on the LNOP® Adt SpO_2 sensor

The preferred attachment sites on adults are the ring and middle fingers of the non-dominant hand. Alternative attachment sites are the other fingers of the non-dominant hand. On immobilized patients or patients whose hands cannot be used as attachment sites, the big or middle toe can be used.

1 Open the packaging and remove the sensor. Hold the sensor with the printed beige side downwards and bend it back to draw off the rear side. Align the sensor so that the receiver can be attached first (Fig. 30).

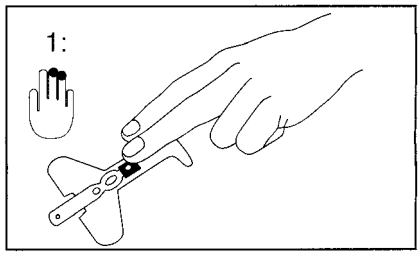


Fig. 30 Positioning the sensor

2 Now press the receiver on the fingertip and wrap the adhesive T ends around the finger (Fig. 31).

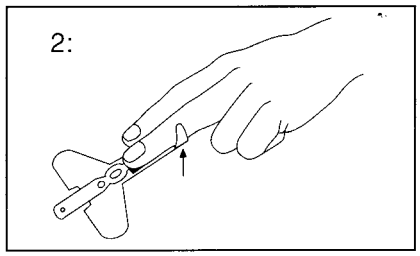


Fig. 31 Positioning the receiver on the fingertip

3 Next wrap the sensor with the transmitter and the finger design around the fingernail, and wrap the flaps downwards, one after the other, around the finger (Fig. 32).

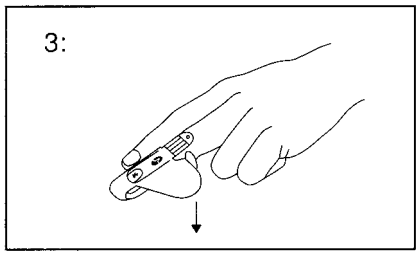


Fig. 32 Aligning the sensor and receiver

4 When the transmitter and receiver are correctly attached, they should be exactly opposite each other (Fig. 33). Check and if necessary correct the sensor's position. The receiver window must be completely covered by the tissue.

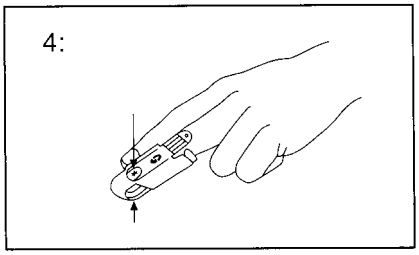


Fig. 33 Correctly attached LNOP® Adt sensor

6.10 Connecting the SpO_2 sensor and patient cable

Hold the sensor's contact blade so that the metal contacts are on the top and the two Masimo symbols on the blade and patient cable are opposite each other. Insert the contact blade into the patient cable until it engages (Fig. 34). Pull carefully on the contact blade to check that it has engaged properly. You can now secure the patient cable to the patient with an adhesive strip.

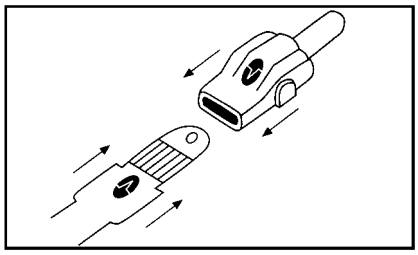


Fig. 34 Connecting the patient cable and sensor contact

6.11 Connecting the SpO_2 patient cable to VitaGuard®

Insert the patient cable's monitor plug into the SpO_2 socket on VitaGuard®. The Masimo inscription on the monitor plug must be on top. You should feel the monitor plug engage.

Fig. 35 SpO_2 socket

6.12 Disconnecting the SpO_2 sensor from the patient cable

Use the thumb and index finger of one hand to carefully press the two buttons on the side of the patient cable's socket (Fig. 36). Carefully pull the end of the sensor to withdraw it.

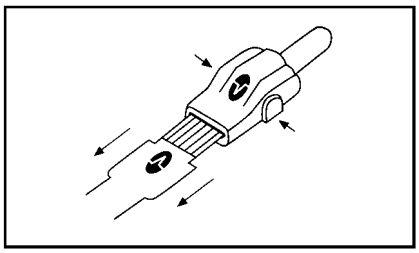


Fig. 36 Disconnecting the sensor from the patient cable

6.13 Disconnecting the SpO_2 patient cable from VitaGuard®

Using your thumb and index finger, carefully press the two levers in the patient cable's monitor plug, and carefully pull out the plug.

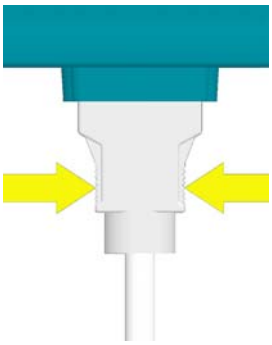


Fig. 37 Two levers for securing and releasing the patient cable plug

6.14 Reusing and refastening SpO_2 sensors

When the SpO_2 sensors are treated with care they can be used several times on the same patient as long as the adhesive surfaces still adhere and the transmitter and receiver windows are cleaned at regular intervals.

Disconnect the sensor from the patient cable before you reattach or refresh it.

- There are replacement adhesive strips available for the LNOP® Neo sensor used on infants.

- When sensors have been in use for a short time only, you can refresh the adhesive surfaces with a cotton swab saturated with a 70% isopropanol solution. Leave the sensor to dry thoroughly in air before reattaching it.
- A sensor can be secured with an adhesive strip on less sensitive patients. Velcro strips are available for more sensitive patients.

Use a new sensor when the old one can no longer be properly secured.

7 Alarms, displays, and views during monitoring

Immediately call the emergency services when a patient remains unconscious after being shaken or addressed.

7.1 Alarm test

CAUTION: When beginning monitoring at a new site, make sure that you can clearly hear the alarm signal and quickly reach the patient. For this purpose, deliberately trigger a technical alarm.

When a patient is connected you can deliberately trigger an alarm by disconnecting the SpO_2 sensor from the SpO_2 patient cable.

7.2 PULSE RATE values based on age groups

Bear in mind that the PULSE RATE drops considerably with increasing age. The doctor must check and, if necessary, adapt the alarm limits for each patient's age group.

The percentage level of arterial blood oxygenation displayed as $\%SpO_2$ normally ranges between 97 and 99%, irrespectively of the patient's age group.

The average pulse rate of an infant is much higher than that of an adult. Accordingly, the alarm limit e.g. for bradycardia (too low a pulse rate) must be set considerably higher for an infant than for an adult patient. As an orientation aid, the following table lists some medically acknowledged approximate pulse rates for various age groups and stress situations.

Age group	Pulse rate / min		
	Sleep	Rest	Stress (e.g. fever)
Newborns	80–160	100–180	max 220
1 week to 3 months	80–200	100–220	max 220
3 months to 2 years	70–120	80–150	max 200
2 to 10 years	60–90	70–110	max 200
10 years and older	50–90	55–90	max 200

7.3 Alarm message priorities in the status line

Fig. 38 Status line on the VitaGuard® display

Physiological alarms have high priority. The text messages of physiological alarms end with three exclamation marks.

!!!

Technical alarms have medium priority. The text messages of technical alarms end with two exclamation marks.

!!

7.4 Physiological and technical alarms

VitaGuard® generates two types of alarms: physiological and technical alarms.

- A **physiological alarm** is generated when VitaGuard® detects values that violate one or more of the set alarm limits for longer than the set period.

There are simple alarm limits, e.g. the LOWER LIMIT for the PULSE RATE, and there are alarm limits based on the interaction of several monitor settings, e.g. the deviation alarms.

- A **technical alarm** is generated when monitoring is no longer reliable for technical defects. When a technical alarm condition occurs, a life-threatening situation may escape detection.

When, for example, a technical alarm condition has occurred, yet at the same time a physiological alarm condition has been detected, the physiological alarm condition has priority and the physiological alarm is reported.

NOTE An alarm mute time of ten seconds follows a technical alarm triggered by problems with the SpO_2 sensor. This delay is to prevent false alarms when the physiological parameters are being recalculated. During the alarm mute time, the bell symbol in the status line is crossed out.

7.5 Differentiating physiological and technical alarm signals

The ALARM TONE PITCH can be set in the SYSTEM menu so that alarms are heard over the prevailing background noise.

The urgency or priority of an acoustic alarm can be recognized by its characteristics described in the following.

High-priority messages emit two sequences of five tones that are repeated every ten seconds.

The interval between each tone packet is two seconds. Also, there is a slightly longer interval between the third and fourth tone of each sequence.

Fig. 39 Characteristics of the high-priority acoustic alarm signal

Medium-priority messages emit a sequence of three tones which is repeated every 5.2 seconds.

7.6 Acoustic information signals

If wished, the alarm unit next to the display can produce a short acoustic signal to accompany each pulse.

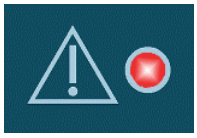
7.6.1 Information signals from the alarm unit next to the display

After the monitor is switched on, an acoustic reminder signal is emitted every twenty seconds until plausible data have been detected.

7.6.2 Information signals from the sound aperture between the sockets

A pulsating tone is emitted if the external power adapter is disconnected and no batteries are installed.

7.7 The visual alarm signals



- A high-priority alarm, i. e. physiological alarm, causes the alarm LED to flash red.

- A medium-priority alarm, i. e. technical alarm, causes the alarm LED to flash yellow.

7.8 Status line displays

During monitoring the status line is displayed in all views.

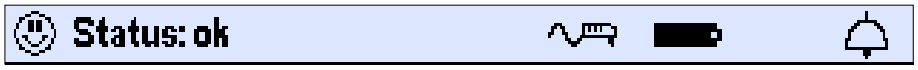


Fig. 40 The status line displayed in all views

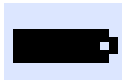
The monitor's text messages appearing on the left are explained in detail in the section "Alarm messages – meanings and other information" on page 62. On the right of the status line are three symbols.

- Power supply

The power supply symbol indicates whether the NA3000-2 external power adapter or the automobile power supply adapter is connected. When a power adapter is connected, the symbol appears as illustrated on the right. Otherwise the symbol is crossed out.

- Battery voltage indicator

The battery voltage indicator depicts the voltage from the batteries. When the block battery is being recharged this symbol is animated, i. e. a filling animation is displayed.



- Alarm indicator

When you interrupt an acoustic alarm by pressing the <Esc> key, the bell symbol is crossed out. To the left of the bell, the remaining alarm mute time is displayed in seconds. This mute time applies only to the current alarm type.

When a new alarm condition is detected, the acoustic alarm is emitted before the alarm mute time has expired.

Pressing the <Esc> key a second time immediately ends the ALARM MUTE TIME.

The alarm bell outline indicates that all acoustic alarm signals are enabled.

In the event of an alarm, the alarm bell is filled out and flashes.

7.9 SpO_2 monitor alarms

After the monitor has been switched on, it can take up to twenty seconds before the first values are displayed.

7.9.1 Physiological SpO_2 alarms

The currently set alarm limits are always displayed. When the displayed SpO_2 value falls below the SpO_2 LOWER LIMIT for longer than

the period set under HYPOXIA ALARM DELAY or exceeds the SpO_2 UPPER LIMIT for longer than the period set under HYPEROXIA ALARM DELAY, an acoustic alarm signal is emitted and the corresponding message is displayed. The affected alarm limit and the alarm LED flash.

Go immediately to the patient when an alarm occurs and check the patient's condition.

When the SpO_2 value returns within the permitted range the alarm is ended automatically. In this case, the affected alarm limit and the alarm LED continue to flash until the <Esc> key is pressed to indicate that an alarm has occurred.

The SpO_2 UPPER LIMIT is deactivated when it is set to 100% (factory setting). We recommend setting an upper limit when the patient is undergoing oxygen therapy.

7.9.2 Technical SpO_2 alarms

The section "Table of technical alarm messages" on page 64 can be consulted for the technical alarm signals and the recommended troubleshooting procedures.

The SpO_2 monitor displays technical alarms with the corresponding messages. Until the problem has been eliminated, the SpO_2 value and the pulse rate are replaced by a question mark symbol. Perfusion and signal IQ are set to zero.

7.10 Pulse rate alarms

After the monitor is switched on, it may take up to twenty seconds before the first values are displayed.

The currently set alarm limits are always displayed.

When the displayed PULSE RATE [PR]

- falls below the LOWER LIMIT for longer than the set BRADYCARDIA DELAY or
- exceeds the UPPER LIMIT for longer than the set TACHYCARDIA DELAY

VitaGuard® emits an acoustic alarm signal and displays the corresponding message. The violated alarm limit and the alarm LED flash.

Go immediately to the patient when an alarm is reported and check the patient's condition.

The alarm is ended automatically when the pulse rate returns within the permitted limits.

Deviation alarms can also be activated in addition to the alarms based on permanently set limits.

7.11 Alarm messages – meanings and other information

The tables in this section list in alphabetical order all the text messages that can appear on the VitaGuard® display together with more detailed explanations and troubleshooting hints.

7.11.1 Order of equal-priority alarm conditions

The numbers in the No. column on the right indicate the internal priorities that VitaGuard® uses to process the respective messages. This is of importance to the doctor only.

7.11.2 Table of physiological alarm messages

Physiological alarms are reported with high priority.

Message	Meaning	Information	No.
Pulse rate and SpO_2!!!	A pulse rate alarm and an SpO_2 alarm have occurred simultaneously.	See the messages and information for "Pulse rate too high/ too low" and "SpO_2 too low".	2
Pulse rate too high!!!	The calculated pulse rate exceeds the set UPPER LIMIT for longer than the set TACHYCARDIA DELAY.	When there is no tachycardia: - Strong artifacts caused by excessive movement trigger false alarms. - The monitor, cable, or sensor is defect. - The set UPPER LIMIT is too low.	7
Pulse rate too low!!!	The calculated pulse rate has fallen below the set LOWER LIMIT for longer than the set BRADYCARDIA DELAY.	When there is no bradycardia: - No pulse is detected. - There are abnormal beats. - The monitor, cable, or sensor is defect. - The set LOWER LIMIT is too high.	6
Pulse rate drop detected!!! (when activated)	The current pulse rate has fallen below the value based on the set AVERAGING INTERVAL by more than the percentage deviation value set under TREND DEVIATION (–).	When there is no pulse rate drop: - The pulse rate and/ or the average pulse rate is incorrectly calculated for the reasons given under "Pulse rate too low".	11
Pulse rate rise detected!!! (when activated)	A pulse rate rise is detected in the same manner as a pulse rate drop, but TREND DEVIATION (+) is used instead.	When there is no pulse rate rise: - The pulse rate and/or the average pulse rate is incorrectly calculated for the reasons given under "Pulse rate too high".	12
SpO_2 too high!!!	The calculated SpO_2 exceeds the set UPPER LIMIT for longer than the set HYPEROXIA ALARM DELAY.	When SpO_2 is not too high: - The sensor is incorrectly attached, e.g. it is too loose or too tight, the transmitter and receiver are too far apart, or they are not exactly opposite each other. - The sensor has become detached - The blood flow is weak or obstructed e.g. by a pressure cuff.	9

Message	Meaning	Information	No.
		- Strong artifacts caused by movements corrupt the signal. - The monitor, cable, or sensor is defect. - The set UPPER LIMIT is too low.	
SpO_2 too low!!!	The calculated SpO_2 has fallen below the set LOWER LIMIT for longer than the set HYPOXIA ALARM DELAY.	See "SpO_2 too high!!!".	8
SpO_2 drop detected!!! (when activated)	The currently measured SpO_2 has fallen below the value based on the set AVERAGING INTERVAL by more than the percentage deviation value set under TREND DEVIATION (–).	When there is no SpO_2 drop: - The present SpO_2 or the value based on the set averaging interval is incorrect for the reasons given under "SpO_2 too high".	13

7.11.3 Table of technical alarm messages

Message	Meaning	Cause or elimination	No.
Check power adapter!!	The measured voltage from the power adapter is less than 8 V or greater than 10 V.	- Check that the stipulated power adapter is being used. - Check and, if necessary, replace the NA3000-2 power adapter.	16
Conflicting SpO_2 limits!!	The SpO_2 LOWER LIMIT has been set higher than the UPPER LIMIT.	- Correct the SpO_2 limits.	20
Hardware fault!!	The monitor has detected an internal fault.	- Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect.	14
Internal data error!!	The internal software monitor has detected a data transfer error.	- Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect.	18

Message	Meaning	Cause or elimination	No.
No cables connected!!	The monitor discovers that both patient cables are not connected.	- Connect the patient cable.	21
No power adapter !!	The power adapter has been disconnected.	- Reconnect the external power adapter or press the <Esc> key.	17
Recharge battery!!	The battery voltage is too low: the monitor can no longer operate reliably	- Operate the monitor with the external power adapter to recharge the block battery, or insert non-rechargeable batteries.	32
Replace batteries!!	The battery voltage is too low: the monitor can no longer operate reliably.	- Insert new batteries or a new block battery or operate the monitor with the external power adapter.	33
SpO_2: Check cable!!	The SpO_2 module reports that the SpO_2 cable is not connected.	- Connect the SpO_2 cable. - Replace the SpO_2 cable, if this message persists.	26
SpO_2: Defective sensor!!	The SpO_2 module reports that the SpO_2 sensor is defect.	- Replace the SpO_2 sensor.	27
SpO_2: Hardware fault!!	The SpO_2 module is not supplying data.	- Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect.	15
SpO_2: Interfer-ence!!	The SpO_2 module detects electromagnetic interfer-ence.	- Locate any interference sources in the direct vicinity and, if necessary, remove them.	30
SpO_2: Pulse search!!	When switched on, at first, the SpO_2 module reports that it is search-ing for the pulse.	- When this message is displayed during monitoring, check whether the sensors are secured and positioned properly.	34
SpO_2: Sensor off!!	The SpO_2 sensor is defect or not connected.	- Check whether the SpO_2 sensor is correctly connected to the cable; if necessary replace the sensor.	28
SpO_2: Too much light!!	The SpO_2 module reports that there is too much light.	- Protect the SpO_2 sensor from light sources, e.g. by covering it.	31

Message	Meaning	Cause or elimination	No.
SpO_2: Unrecog-nized sensor!!	The SpO_2 module reports that an unrecognized sensor is connected.	- Replace the SpO_2 sensor (use only the sensors from Masimo Inc.).	29

7.12 Table of information messages

Message	Cause	Meaning	No.
Calculating pulse rate	The current pulse rate cannot be displayed while it is being calculated.	The current pulse rate is displayed after it has been calculated.	37
Internal battery too low	The internal battery for alarms during a power failure is depleted.	- The monitor is defect i. e. the internal battery needs to be replaced by a technician.	39
SpO_2: Low perfusion	The SpO_2 module reports that the blood flow is too weak.	- Either use a different attachment site, or set SENSITIVITY to MAXIMUM in the SpO_2 menu.	35
SpO_2: Low signal IQ	The SpO_2 module reports that the signal quality is low.	- Use a different attachment site, or check for the presence of light or electromagnetic interference sources in the vicinity. - Whenever possible, prevent vigorous movements by the patient.	36
Status: ok	No messages		40

8 Alarm and monitor settings

The functions described in this section can be accessed only when the doctor has set SETTINGS PROTECTION to LIMITED in the SYSTEM menu. This setting requires a code.

The function ADMIT NEW PATIENT in the SYSTEM menu overwrites all earlier settings.

The set alarm limits and other monitor parameters are stored and retained when the monitor is switched back on after a battery change.

8.1 Safety instructions for the alarm settings

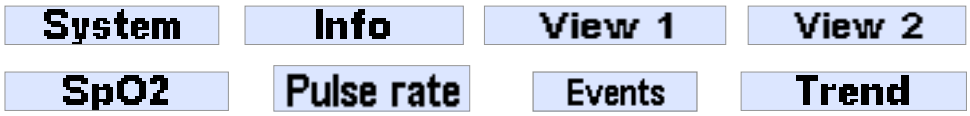
It is important that the doctor responsible sets new alarm limits and monitor parameters for each patient and for each new medical situation. Never change alarm limits without consulting the treating doctor.

Never set the alarm limits to extreme values that render the monitoring system useless.

When you have been given a code for changing alarm limits, it is important that you treat this code as confidential. Life is in danger when alarm limits are not adapted specifically to each and every patient.

8.2 Summary of views and menus

The views presented here are intended to provide extensive information on the monitoring situation. When SETTINGS PROTECTION is set to LIMITED, they can be accessed with the direction keys ◁ and ▷.



The keys △ and ▽ let you access more detailed information and enter menus for changing monitor settings.

- The △ or ▽ key takes you from the SYSTEM view to the SYSTEM menu. The first setting is highlighted.
- The △ or ▽ key leafs through pages on the INFO display.
- The △ or ▽ key takes you from VIEW 1 or 2 to the menu "MANUAL DATA STORAGE or TRANSMIT DATA". This is explained in the corresponding section on page 93.
- The SpO_2, and PULSE RATE displays each feature a menu for adjusting the respective settings and can be accessed with the △ or ▽ key. The first setting is highlighted.
- The △ or ▽ key takes you from the EVENTS or TRENDS views to detailed views, WAVEFORMS, and TRENDS.

8.3 Additional views

When the doctor has configured VitaGuard® so that also the caregivers can change settings, i.e. SETTINGS PROTECTION is set to LIMITED, VIEWS 2 is also activated in addition to VIEW 1. VIEW 1 is explained in the section "The display" on page 41.

8.3.1 VIEW 2 – Large data presentation and waveforms

VIEW 2 displays in large digits the current values for the monitored vital functions and, on the right in smaller digits, the set alarm limits.

Also, each section on the left presents a waveform of the monitored vital function.

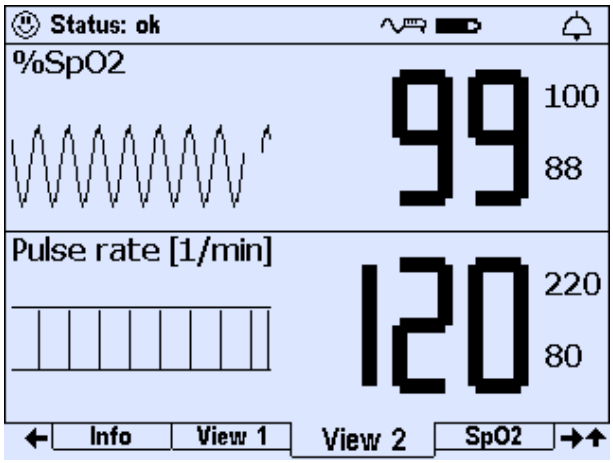


Fig. 41 View 2

8.4 Changing the settings

Use the direction keys to highlight a menu option or an entry in this option. Once you have highlighted the option you want, press the <Enter> key to change it. When you do not want to keep your changes, press the <Esc> key.

The △ key takes you to the menus. The first entry in the list is highlighted. Use the ▽ key to highlight the setting LCD BRIGHTNESS (“Changing multiple-component settings” is explained on page 86 for the doctor and qualified medical staff).

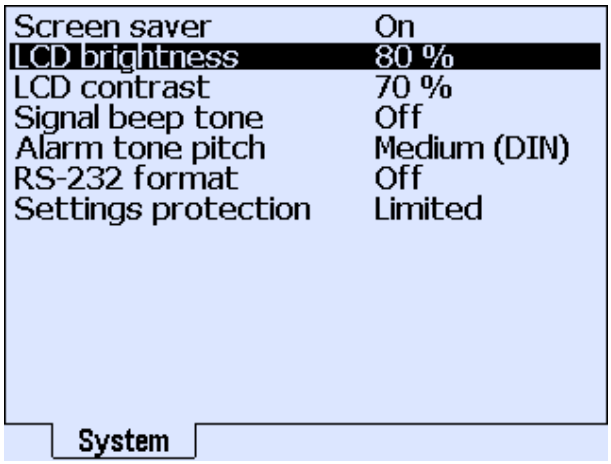


Fig. 42 Menu system, “LCD brightness: 80%” highlighted

Press the <Enter> key. A window appears where you can change the old value.

Use the △ and ▽ keys to change the highlighted value.

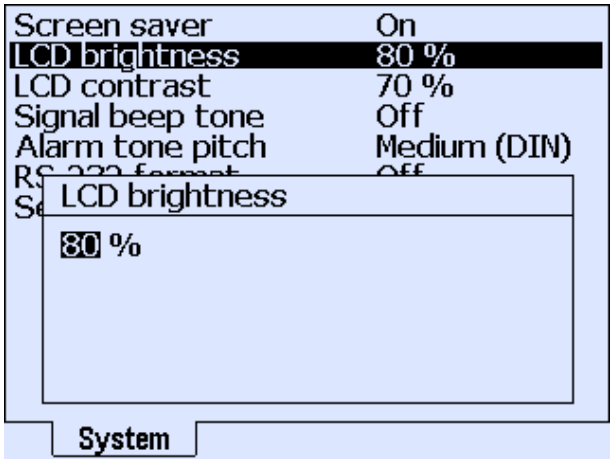


Fig. 43 System, "LCD brightness" highlighted in the change window

Pressing the <Enter> key after changing a value causes a prompt to appear with ACCEPT: No highlighted. Press the ◁ key to highlight ACCEPT: YES.

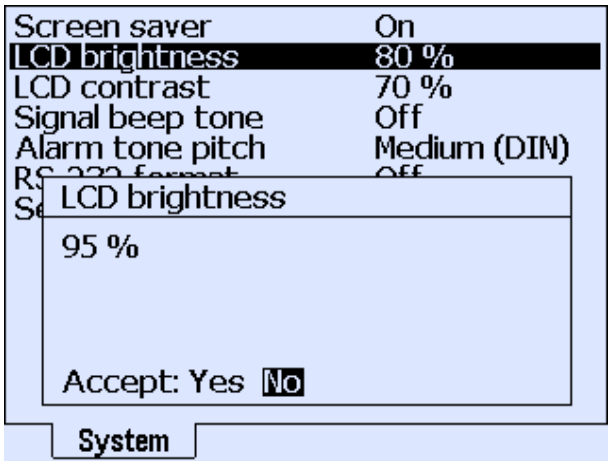


Fig. 44 System, accept change to LCD brightness highlighted

Confirming the prompt ACCEPT: YES with the <Enter> key displays the changed value in the list. To exit the menu press the <Esc> key.

8.5 SYSTEM menu – general settings

NOTE You can familiarize yourself with the menus without changing values. Simply press the <Esc> key to exit each menu and submenu without saving changes.

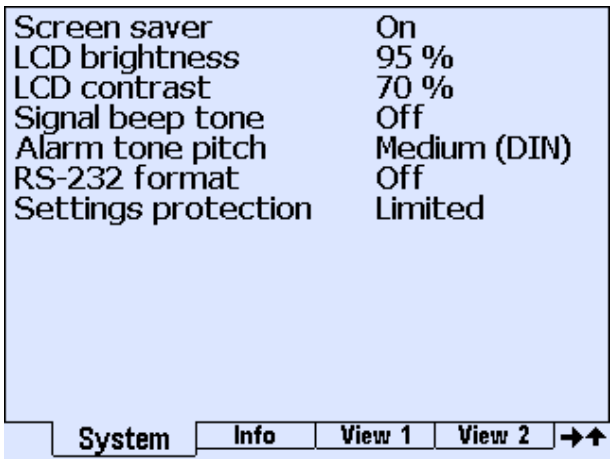


Fig. 45 System menu – general settings

8.5.1 System\ Screen saver (Off/ On)

When Screen saver is set to On, an animation appears on the display when no key has been pressed for five minutes.

When you press a key or an alarm is triggered, the previous mask is displayed again.

8.5.2 System\ LCD brightness

You can set the LCD brightness from 0% to 100% in steps of 5%. When 0%, the display's backlight illumination is switched off. The factory setting is 95%.

8.5.3 System\ LCD contrast

You can set the display's contrast from 0% to 100% in steps of 5%. The factory setting is 70%.

8.5.4 System\ Signal beep tone

You can configure the monitor to emit a brief signal tone with every detected Pulse.

When this tone disturbs the patient or caregivers, choose the setting Off.

The factory setting is Off.

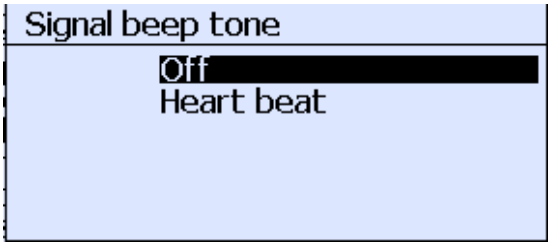


Fig. 46 System\ submenu "Signal beep tone"

8.5.5 System\ Alarm tone pitch

You can set the pitch of the acoustic alarm signals to Low, Medium, or High so that they can be heard over the expected background noise. The DIN settings (DIN) match the alarm tone characteristics as described from page 58 on in the section “Differentiating physiological and technical alarm signals”. As an alternative, you can set the alarm tone characteristic (gtm) as familiar from other getemed devices. The factory setting is Medium.

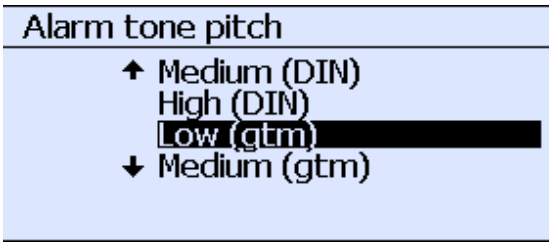


Fig. 47 System\ submenu “Alarm tone pitch”

8.5.6 System\ RS232 format

This submenu lets you assign the format for online data output from the AUX serial port.

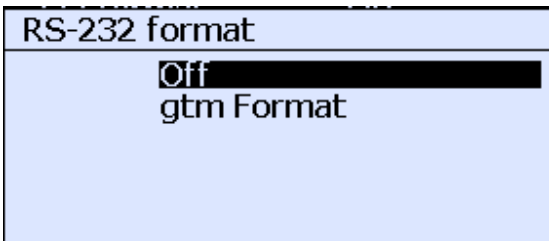


Fig. 48 System\ RS232 format

8.5.7 System\ Settings protection On, Limited, Off

The codes that protect the alarm defaults from unauthorized changes must be given by the doctor to those persons only whom the doctor judges to be adequately informed about monitoring and their responsibility for the patient. The doctor should point out that the code must be treated as confidential, that settings should be changed at the doctor’s request only, and that all changes must be confirmed by the doctor.

VitaGuard® provides the following three settings for Settings protection.

- **Settings protection ON** deactivates all options to change monitor settings. The display presents only View 1, the Info display, and the System menu.
- **Settings protection Limited** enables access to all views and menus. Of all the monitor settings, however, only the alarm limits can be changed.
- **Settings protection Off** enables all views and menus and allows changes to all monitor settings.

The factory setting is Settings protection Limited.

After highlighting the function Settings protection, press the <Enter> key to open a submenu.

- This submenu always displays Settings protection as “00” irrespectively of the current setting. Pressing the <Enter> key activates Settings protection.
- When you enter a code Settings protection appears as Limited.
- When you enter a different code, Settings protection appears as Off.

When the wrong code has been entered three times Settings protection cannot be so easily deactivated. In this case, consult your authorized dealer.

8.6 SpO_2 display and menu

The ▷ key takes you from View 1 or 2 to the SpO_2 display. Here you can open the menu with the △ or ▽ key. Having highlighted a row, press the <Enter> key to change its contents.

8.6.1 SpO_2 view

The top half of the display presents:

1 the status line

2 the current value with the set alarm limits

3 the current three-minute trend views that update the last value every two seconds

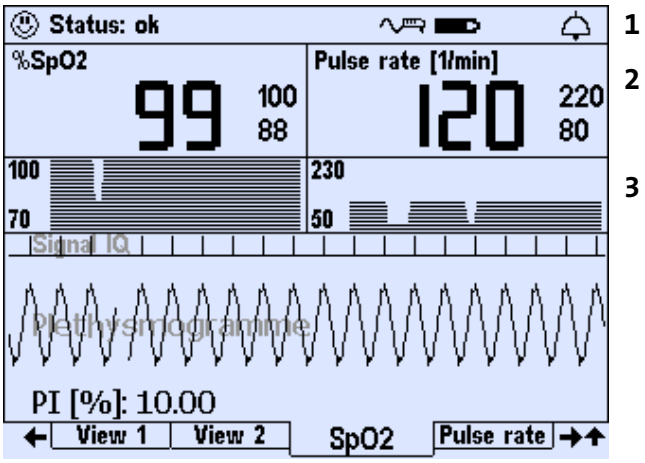


Fig. 49 SpO_2 view, plethysmogram, perfusion index, and signal IQ

The SpO_2 trend displays the SpO_2 values between 70 and 100% over the last three minutes.

The first row under the trend view is the SIGNAL IQ as vertical bars, the second the PLETHYSMOGRAMME. At the bottom perfusion index [PI] and pulse rate [PR] are displayed.

When the monitor is switched on, it can take up to twenty seconds before the first values are displayed.

Bear in mind that the plethysmogram is NOT proportional to the pulse volume. A regular plethysmogram, for example, indicates that the SpO_2 sensor is correctly secured.

Every time the SpO_2 monitor detects a pulse beat a vertical bar appears in the SIGNAL IQ row. The higher this bar, the better the signal from the SpO_2 sensor. A high SIGNAL IQ indicates that:

- the sensor is correctly attached,
- an adequately strong signal is detected for the arterial blood flow,
- the patient does not move or is not moved too vigorously.

The calculated percentage value for PERFUSION (PI) can vary between 0 and 20%. When this value is very low, SpO_2 and the pulse rate are

no longer monitored. When the SENSITIVITY in the SpO_2 menu is set to MAXIMUM, the cut-off limit is 0.02%; when set to STANDARD, this limit ranges from 0.5 to 0.02%, depending on the signal quality.

The principal of operation for this calculation can be found in the section “Measuring principle for the SpO_2 monitor” on page 103.

8.6.2 SpO_2 menu – alarm settings (SETTINGS PROTECTION LIMITED)

The SpO_2 menu lets you view and change the current SpO_2 alarm settings.

Changes are permitted only when SETTINGS PROTECTION is set to LIMITED in the SYSTEM menu.

Factory settings are shown in bold type.

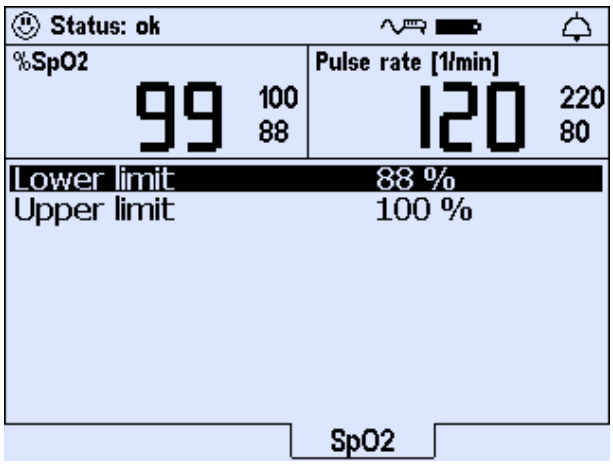


Fig. 50 SpO_2 menu for viewing and setting alarm limits

LOWER LIMIT ..... 50, 51 ... **88** ... 99, 100 %
Lower alarm limit for the measured arterial oxygen saturation; an alarm is reported when the measured value falls below this limit for longer than the set HYPOXIA ALARM DELAY

UPPER LIMIT ..... 50, 51 ... 88 ... 99, **100** %
Upper alarm limit for the measured arterial oxygen saturation; an alarm is reported when the measured value exceeds this limit for longer than the set HYPEROXIA ALARM DELAY

8.7 PULSE RATE display and menu

The ▷ key takes you from VIEW 1, or 2 to the pulse rate display. From here you can open the menu with the △ or ▽ key. When a row is highlighted, press <Enter> to change the corresponding value.

8.7.1 PULSE RATE display

The top half of the display presents:

1 the status line

2 the current values with the set alarm limits

3 the current three-minute trends that update the last value every two seconds

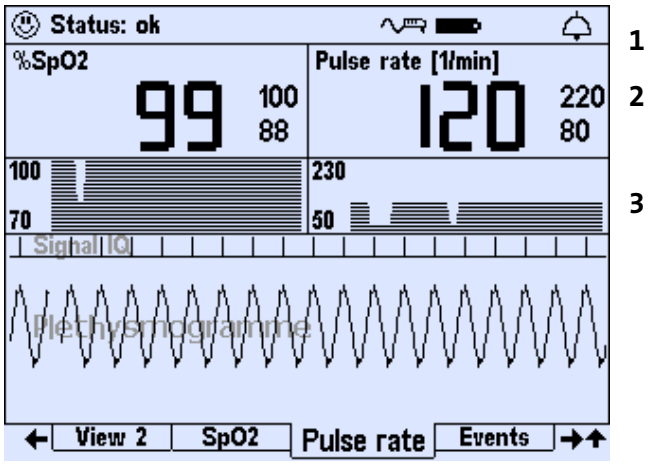


Fig. 51 Pulse rate display

The pulse rate trend display presents the pulse rate over the last three minutes. This display varies with the set age group:

	0 TO 2 YEARS	2 TO 6 **YEARS**	>6 YEARS
PULSE RATE TREND DISPLAY [PER MIN]	between 230 and 50	between 180 and 50	between 150 and 45

The bottom half of the display presents the plethysmogramme. A small vertical bar indicates every detected pulse.

8.7.2 PULSE RATE menu – alarm settings (SETTINGS PROTECTION LIMITED)

The PULSE RATE menu lets you view and, if necessary, change the current pulse rate settings. You may have to adapt the default age

group alarm limits to the current patient. These settings can be changed only when SETTINGS PROTECTION has been set to LIMITED in the SYSTEM menu.

Different pulse rate alarm limits can be set as the default values for each age group:

Default	0 TO 2 YEARS	2 TO 6 YEARS	> 6 YEARS
LOWER PULSE RATE LIMIT [/MIN]	80	60	55
UPPER PULSE RATE LIMIT [/MIN]	220	150	140

The pulse rate's LOWER LIMIT can be set from 30 to 180 beats and the pulse rate's UPPER LIMIT from 100 to 255, each in steps of five beats per minute.

Factory settings are shown in bold type.

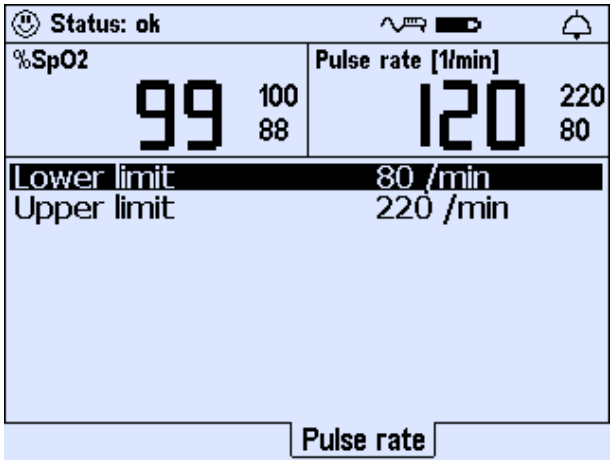


Fig. 52 Pulse rate menu for viewing and setting alarm limits

LOWER LIMIT (pulse rate) ..... 30, 35 ... **80** ... 175, 180/min
Lower limit for the pulse rate; an alarm is reported when the pulse rate falls below this limit for longer than the set BRADYCARDIA DELAY

UPPER LIMIT (pulse rate) ..... 100, 105 ... **220** ... 250, 255/min
Upper limit for the pulse rate; an alarm is triggered when the pulse rate exceeds this limit for longer than the set TACHYCARDIA DELAY

9 Information for the doctor and qualified medical staff

The treating doctor is responsible for monitoring with VitaGuard®. This also applies to ambulatory monitoring.

This section contains all safety and settings information that only the treating doctor can make decisions on. Remember that all the information and instructions in the sections “Intended use” on page 14 and “Safety” on page 18 must also be observed.

Only getemed AG personnel or authorized dealers certified by getemed AG as medical product advisers in accordance with § 31 MPG (German Medical Products Act) may instruct the doctor and the qualified medical staff on how to handle and use VitaGuard®. This certification is awarded only to those persons that have received adequate training from getemed AG for its products.

9.1 Safety instructions

The safety instructions in this section address special technical and medical issues that are of particular importance to the doctor and qualified medical staff.

9.1.1 Preparing for a new patient

When more than one VitaGuard® monitor with differing settings are used in the same environment, there is a risk of mixing monitors and a particular patient may be monitored with unsuitable settings. For this reason check the currently set alarm limits every time the monitor is switched on.

It is important that VitaGuard® is configured so that false alarms are avoided to the greatest possible extent. Frequent false alarms can prove detrimental to the alertness of caregivers.

When VitaGuard® is to be used for a new patient, the doctor or the qualified medical staff are obliged to take the following important precautionary measures.

- Place used consumables such as sensors in a plastic bag before disposing of them in household or medical waste.
- Clean the device and disinfect all cables (e.g. as described in the guidelines from the Robert Koch Institute).
- Insert new batteries or a fully charged block battery.
- Select the age group in SYSTEM\ ADMIT NEW PATIENT as explained under "SYSTEM\ ADMIT NEW PATIENT – restoring factory settings" on page 87.
- Check that the monitor settings are suitable for the patient and, if necessary, adapt them.
- Consider that the monitor settings may need to be changed at a future date and, as appropriate, arrange appointments to change these settings.
- Check that the acoustic alarm signal is loud enough to be heard over the prevailing or expected noise levels in the monitor's environment.
- When necessary, set SETTINGS PROTECTION to LIMITED.
- When necessary, train caregivers in the necessary resuscitation measures.

9.1.2 Connections to the USB and AUX ports

The USB port is designed to transfer data to a PC. The AUX port can interface with a modem for remote data transfer.

Observe the standard DIN EN 60601-1-1 for connections to systems consisting of multiple medical devices and to systems consisting of medical and non-medical devices.

A device must comply with the regulations under DIN EN 60601-1 for medical devices or under DIN EN 60950 for communication technology devices before it is connected to the USB or AUX ports. In addition, the leakage current from the VitaGuard® must be measured as stipulated in the standard DIN EN 60601-1-1. This leakage current must not exceed 100 µA. Only qualified medical device technicians can check whether the leakage current conforms to the standards.

When several devices are connected to each other, the individual leakage currents can add up and may pose a risk to the patient.

Do not connect printers, cameras, scanners, or other devices.

9.1.3 VitaGuard® and other medical devices

When VitaGuard® is to operate at the same time as a defibrillator, the monitoring results may be invalid for a short time. In addition, defibrillation can damage the cables. Check the monitoring system after defibrillation.

Bear in mind that an external defibrillation pulse can be attenuated. A test in accordance with DIN EN 60601-2-49 showed that defibrillation pulses emitted during monitoring are attenuated by less than 10 %.

Do not use VitaGuard® in conjunction with HF surgical equipment, TENS devices, or nerve stimulators.

VitaGuard® correctly interprets pacer pulses with amplitudes greater than 5 mV, so VitaGuard® can be used on patients with pace makers.

Warn your pacemaker patients that the displayed pulse rate may possibly be affected by stimulating pulses. Point out to the caregivers that they must carefully observe pacemaker patients.

Do not operate VitaGuard® near MRI devices (magnetic resonance imaging) or other systems that generate strong electromagnetic fields. Leads can heat up by induction, causing fire in the cables. The

strong magnetic fields generated by magnetic resonance image devices can cause permanent damage to VitaGuard®.

9.1.4 Safety instructions for the doctor – SpO_2 monitor

Regard the SpO_2 monitor as an early warning device. When the SpO_2 monitor tends towards too low blood oxygen saturation, blood samples should be analyzed to clarify the situation.

Intravascular coloring agents and the associated possible rise in carboxyhemoglobin (COHb) and methemoglobin (MetHb) levels can lead to imprecise $Sp0_2$ measurements.

An intra-aortic balloon pump can distort these values.

Circulatory centralization, i.e. when the organism contracts the vessels to reduce the flow of blood to the extremities, can suppress or otherwise distort the monitored SpO_2 values. Circulatory centralization can arise when e.g. patients are anesthetized, suffer from shock, or are under great physical strain. Ear sensors, for example, are available for short-term applications.

A pulse oximeter may not be used as an apnea monitor.

9.2 INFO display

The INFO display quickly presents the doctor with a summary of the monitor settings and data. Other INFO windows can be accessed with the direction keys △ and ▽.

The current page number and the total number of pages are displayed in the top right. For example, “1/8” means “the first of eight pages”.

9.2.1 Info\ Last status messages

The last status messages provide information on the directly preceding monitoring period. Here you can see when and why a message appeared.

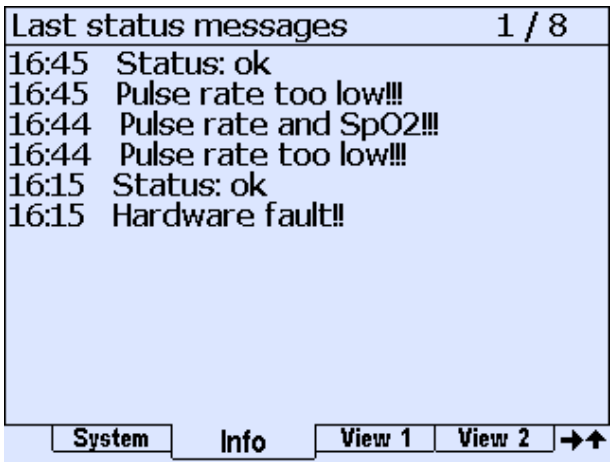


Fig. 53 Info\ Last status messages

9.2.2 Info\ General

- Internal battery

This displays the state of the Internal battery permanently installed in VitaGuard®.

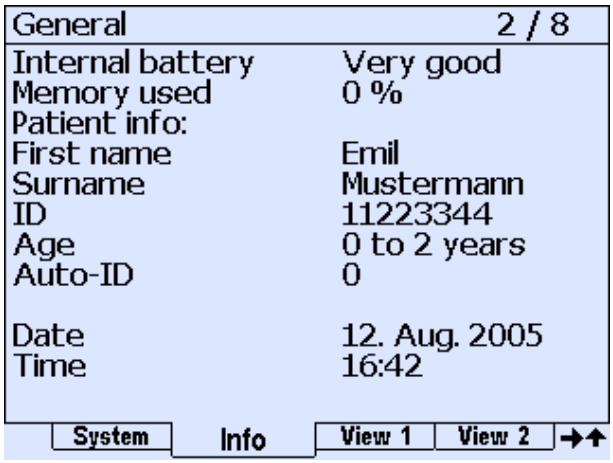


Fig. 54 Info\ General

- Patient name/ Patient ID

The patient's name and ID are displayed when VitaWin® has transferred these from a PC to VitaGuard® or when they have been keyed in as explained in the section "System\ Admit new patient – restoring factory settings" on page 87.

- Age

This displays the age group that has been set as explained in the section "System\ Admit new patient – restoring factory settings" on page 87.

- AUTO-ID

This displays the ID number that is automatically assigned every time the ADMIT NEW PATIENT function is executed.

- DATE, TIME

This displays the date and time of the internal clock which can be set in the SYSTEM menu.

9.2.3 INFO\ MEASUREMENTS: SpO_2

INFO\ MEASUREMENTS: SpO_2 displays various average values for SpO_2 calculated since the monitor was switched on.

These values are lost when the monitor is switched off.

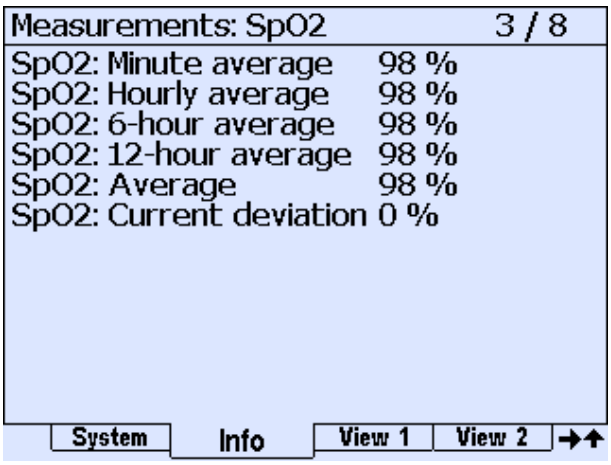


Fig. 55 Info\ Measurements: SpO_2

SpO_2: AVERAGE is calculated over the AVERAGING INTERVAL set in the SpO_2 menu. The CURRENT DEVIATION shows how much the current SpO_2 deviates from the AVERAGE in percent. This deviation is used for reporting deviation alarms when SpO_2 ALARMS in the SpO_2 menu has been set to LIMITS & TRENDS.

9.2.4 Info\ Measurements: Pulse rate

Info\ Measurements: Pulse rate displays the various average pulse rate values calculated since the monitor was switched on.

These values are lost when the monitor is switched off.

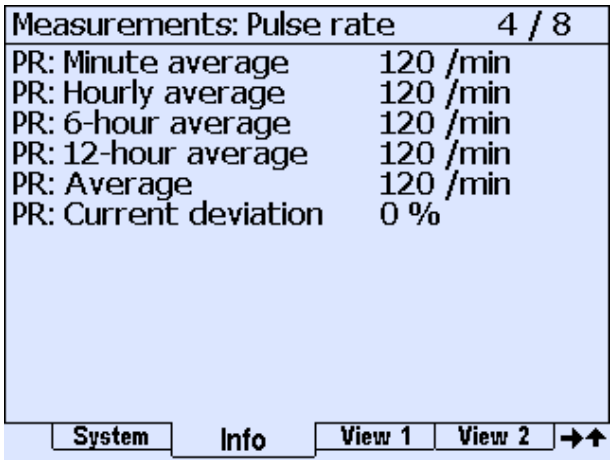


Fig. 56 Info\ Measurements: Pulse rate

PR: Average is calculated over the Averaging interval set in the Pulse rate menu. The Current deviation shows how much the current pulse rate deviates from the Average in percent.

9.2.5 Info\ Settings: Oximeter

This window presents all the settings for SpO_2 monitoring that are not shown in Views 1 to 3.

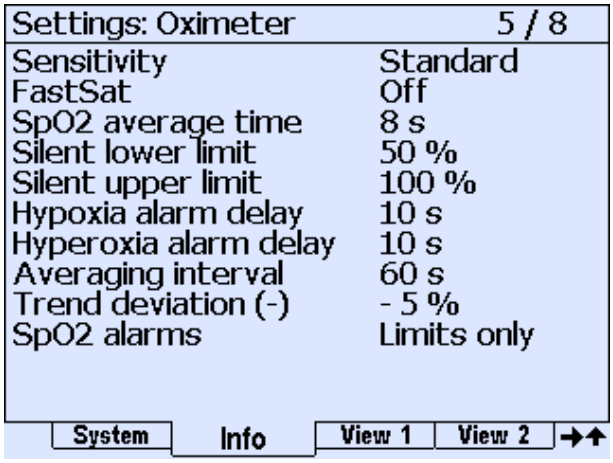


Fig. 57 Info\ Settings: Oximeter

9.2.6 Info\ Settings: Pulse rate

This window presents all the settings for pulse rate monitoring that are not shown in Views 1 to 3.

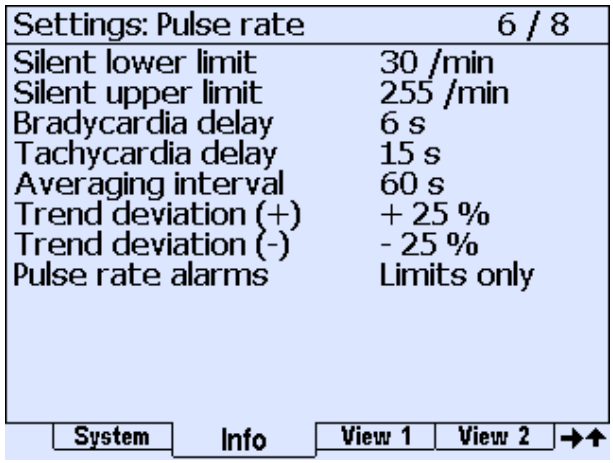


Fig. 58 Info\ Settings: Pulse rate

9.2.7 Info\ Memory/ Internet

This displays the current Memory used and the total Memory size.

Also displayed is Telephone, i.e. the modem number that the monitor automatically dials for remote data transfer. This telephone number must be loaded by the evaluation software VitaWin® and cannot be edited directly in the monitor.

Here you can also view the details for transferring data as an e-mail attachment.

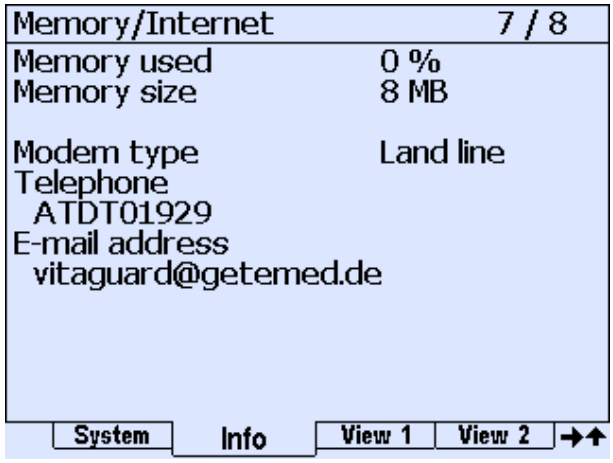


Fig. 59 Info\ Memory

9.2.8 Info\ Versions

Info\ Versions displays the software and hardware version numbers.

The software and hardware from MASIMO for monitoring SpO_2 are also displayed, followed by the monitor's serial number (SN).

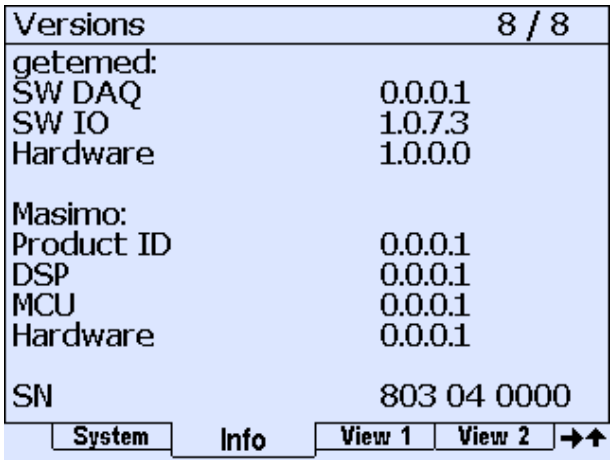


Fig. 60 Info\ Versions

9.3 Settings in the SYSTEM menu (SETTINGS PROTECTION OFF)

When SETTINGS PROTECTION is switched off in the SYSTEM menu, the doctor can configure Vita-Guard® for specific monitoring requirements.

Use the direction keys to highlight an entry. When you want to change the entry, press the <Enter> key. Pressing the <Esc> key discards any changes without saving.

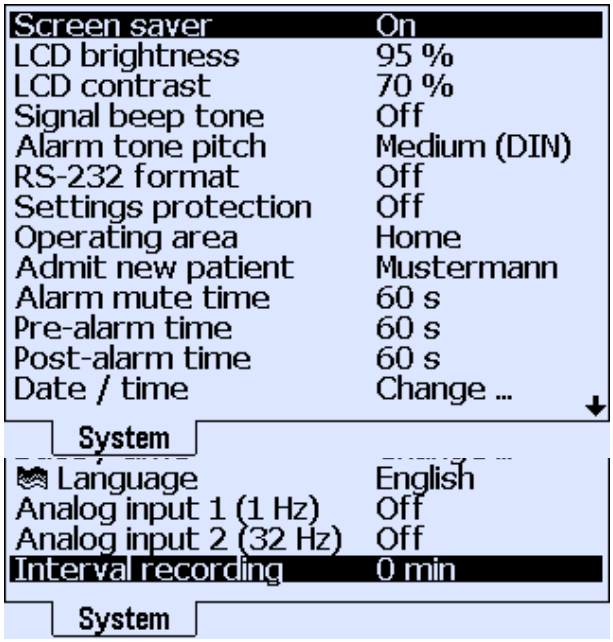


Fig. 61 Separately protected settings in the System menu

9.3.1 Changing multiple-component settings

The following example for changing the date and time in the SYSTEM menu is intended to explain how you can change system settings consisting of several components.

Use the ▽ key to highlight the entry DATE/ TIME.

Press <Enter>. A window appears for changing the old entry.

Use the keys ◁ and ▷ to highlight the component you want to change.

The highlighted value is changed with the keys △ and ▽.

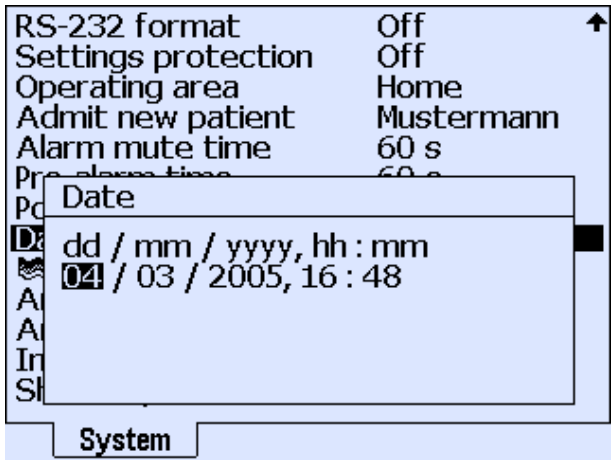


Fig. 62 System\ Date/ time

After changing a value, pressing the <Enter> key a second time causes a prompt to appear with ACCEPT: NO highlighted. Press the ◁ key to highlight ACCEPT: YES. Confirming the prompt ACCEPT: YES with the <Enter> key displays the changed value in the list. To exit the menu press the <Esc> key.

9.3.2 SYSTEM\OPERATING AREA: HOME or CLINIC

OPERATING AREA lets you decide whether the value you have entered for SETTINGS PROTECTION is retained the next time VitaGuard® is switched on. When you select HOME, SETTINGS PROTECTION is ON when the device is next switched on. When you select CLINIC, SETTINGS PROTECTION is set to the selected value when the device is next switched on.

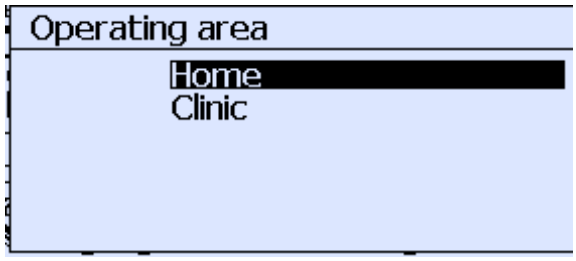


Fig. 63 Operating area: Home or Clinic

9.3.3 SYSTEM\ ADMIT NEW PATIENT – restoring factory settings

IMPORTANT: This deletes all stored data and all monitor settings for a specific patient.

Check that the new monitor settings are suitable for the patient.

All data are deleted and all user settings are restored to the factory values, so you are prompted whether you want to CONTINUE. Press the ◁ key to highlight ACCEPT: YES and then the <Enter> key.

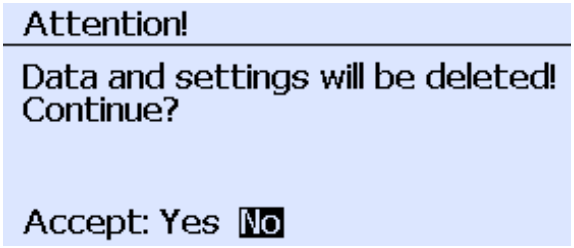


Fig. 64 Warning before changes under System\ Admit new patient

The submenus for ID, FIRST NAME, and SURNAME are displayed one after the other.

Use the ◁ and ▷ keys to position the cursor.

Use the △ and ▽ keys to enter letters and numbers.

Press the <Enter> key after you have entered your data in each submenu.

These inputs are optional and can be skipped by pressing the <Enter> key.

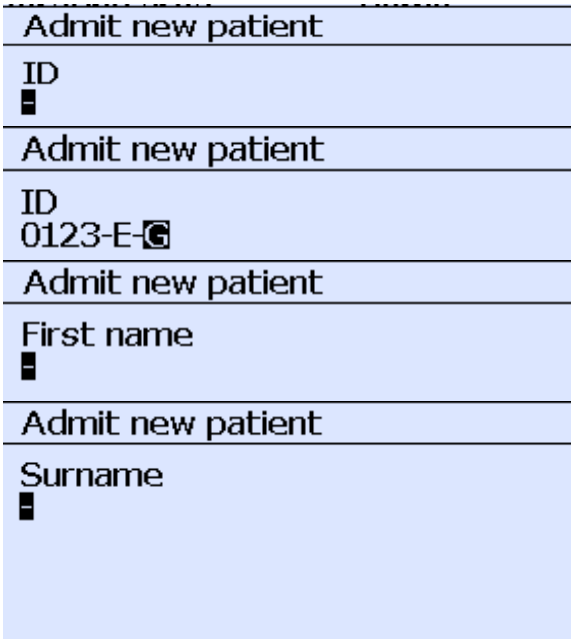


Fig. 65 System\ ID, First name, and Surname

Pressing the <Enter> key to confirm your entry in the SURNAME menu opens the submenu for setting the age group. Here too, press the <Enter> key to confirm your age group settings.

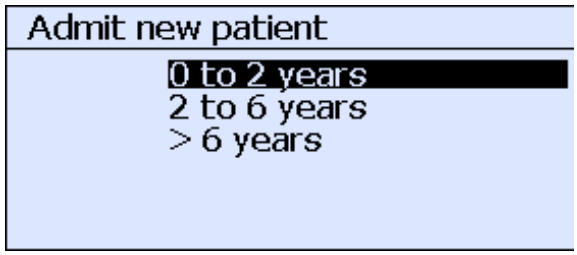


Fig. 66 System\ Age group

Use the ◁ key to highlight ACCEPT: YES and then press the <Enter> key, your settings for the new patient are stored.

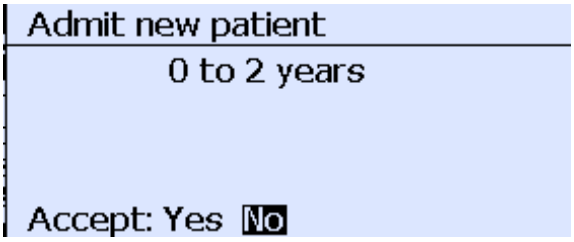


Fig. 67 Confirming the age group setting

The ADMIT NEW PATIENT function restores the factory settings.

VitaGuard® is delivered with alarm limits for patients in the 0 TO 2 YEARS age group.

The following settings vary with the age group:

- the LOWER LIMIT and the UPPER LIMIT in the PULSE RATE menu

The table lists the factory settings for each age group:

	0 TO 2 YEARS	2 TO 6 YEARS	>6 YEARS
LOWER PULSE RATE LIMIT [/MIN]	80	60	55
UPPER PULSE RATE LIMIT [/MIN]	220	150	120

All other settings are not specific to age groups.

The values set last are retained when VitaGuard® is switched off and when the supply network or batteries fail to provide power.

9.3.4 SYSTEM\ PRE- and POST-ALARM TIME

In the event of an alarm, data for the PRE-ALARM and POST-ALARM TIMES set here are stored in addition to the duration of the alarm. These times can be set from 30 to 180 seconds for PRE-ALARM and from 30 to 250 seconds for POST-ALARM in steps of ten seconds.

Also the menu item “SYSTEM\ INTERVAL RECORDING” explained on page 90 records data for the duration of the pre-alarm and post-alarm times.

9.3.5 SYSTEM\ ALARM MUTE TIME

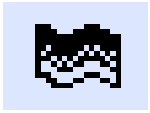
In order to allow caregivers to tend to a patient in peace during an alarm, the acoustic alarm signal can be temporarily deactivated with the <Esc> key. Set the ALARM MUTE TIME to 30, 60, 90, or 120 seconds as required. The acoustic alarm signal is automatically reactivated after this time.

9.3.6 System\ Date/ time

How to change these values is explained in the section “Changing multiple-component settings” on page 86. This is used to set the current date and the current time, e.g. for summer and winter times.

9.3.7 System\ Language

The menu option Language is marked with a flag symbol in the event that you do not understand the set language.



The submenu Language lets you choose between the languages supported by your monitor version.

9.3.8 System\ Analog input 1 + 2

You can activate and deactivate the two analog inputs separately. Both analog inputs have an input range from 0 to 2.5 V. An analog signal at input 1 (when activated) is scanned with 1 Hz and stored, a signal at input 2 is scanned with 32 Hz and stored.

9.3.9 System\ Interval recording

The doctor can use Interval recording for specific situations and can set an interval in steps of ten minutes after which monitored data are again stored. After each of these intervals, the monitor stores data for the Pre-alarm and Post-alarm times. The setting 0 min deactivates interval recording.

9.4 Data storage functions

The function Admit new Patient in the System menu overwrites all the currently stored data and restores the factory settings. If necessary, transfer the data beforehand to a PC.

The memory contents of VitaGuard® are also retained when the power adapter or batteries fail.

VitaGuard® features the following data storage functions:

- EVENT storage (automatic storage of ALARMS and SILENT ALARMS or MANUAL STORAGE)
- TREND storage (automatically for max 72 hours)
- INTERVAL storage (set in the SYSTEM menu)
- LONG TERM storage (automatically for max eight hours)
- PROTOCOL storage (automatic)

The VitaGuard® display lets you view stored EVENTS and stored TRENDS. LONG TERM and PROTOCOL storage can be evaluated on a PC only. The “Summary of stored signals and data” on page 96 presents the signals and sample rates for the respective memory. The currently utilized memory capacity is shown on the INFO display. The installed memory can store up to 200 events of two minutes each.

9.5 EVENT storage

Please bear in mind that you must wait for the POST-ALARM TIME to expire after an alarm has ended before the current alarm event can be completely stored.

The time of occurrence and the length of the stored data are stored for every alarm event. The section “Summary of stored EVENTS” on page 94 explains the symbols in the columns for each physiological parameter [⬆ ⬇ (⬆) (⬇) X P].

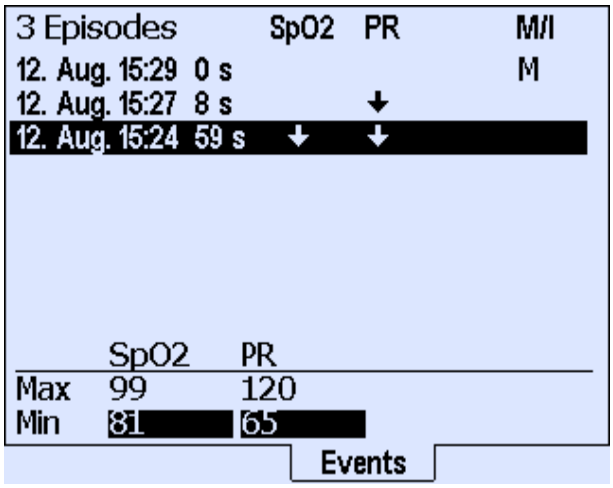


Fig. 68 List of the stored events

M/I marks the episodes that have been stored via MANUAL STORAGE or INTERVAL RECORDING set in the SYSTEM menu. The minimum and maximum values of the respective physiological parameters are seen at the bottom of the window.

Highlighting an alarm event with the direction keys △ and ▽ and pressing the <Enter> key opens a mask with initial detailed information on this event. Highlighting WAVEFORMS and pressing the <Enter> key displays the waveforms recorded with this event.

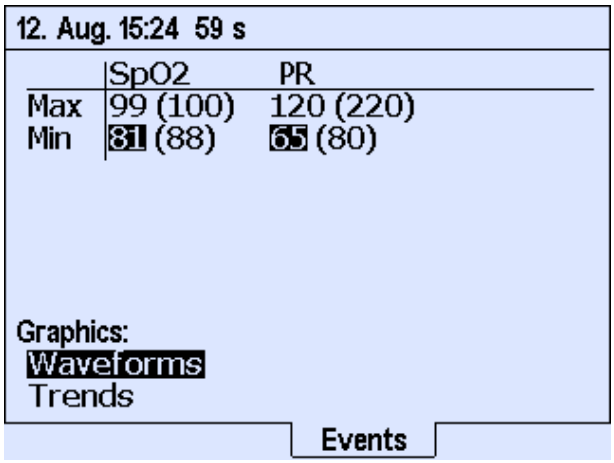


Fig. 69 Detailed information on a highlighted event

The black symbol between the displayed times for the start and end of the event marks the section of the stored event currently displayed. The two small vertical bars mark the start and end of the alarm event itself.

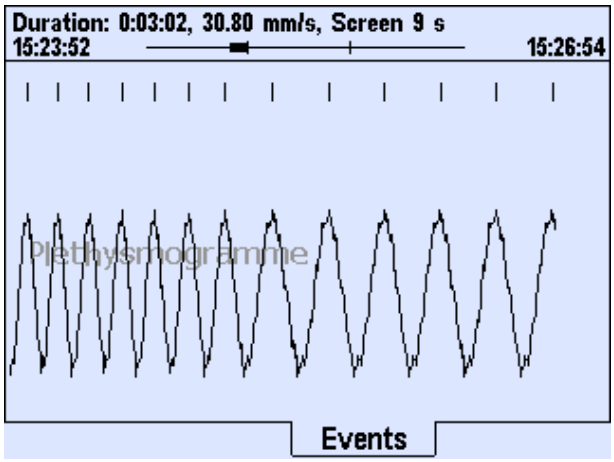


Fig. 70 Stored waveforms

Highlighting TRENDS and pressing the <Enter> key displays the TRENDS for SpO_2 and pulse rate recorded with this alarm.

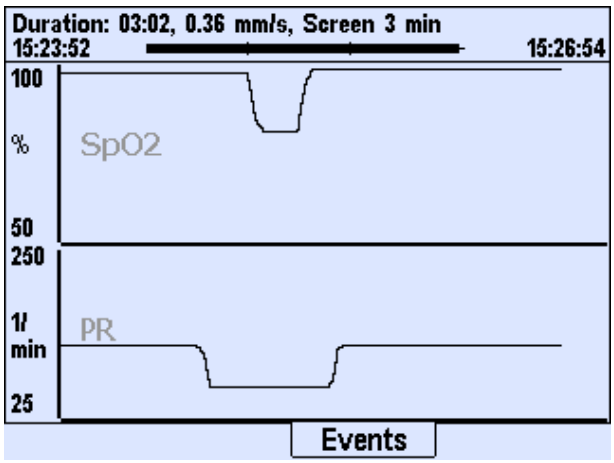


Fig. 71 Stored trends

9.5.1 Silent alarm limits

The monitor also lets you store signal sequences that are important for evaluating the selected alarm limits. To store these so-called “silent alarms”, activate Silent Alarm limits in the corresponding monitoring menu.

When measurements violate the Silent alarm limits, the current episode is stored without triggering an acoustic or visual alarm. For example, when the Silent lower limit is set higher than the Lower limit in the Pulse rate menu, silent bradycardia alarms are stored.

9.5.2 Manual data storage or Transmit data

The △ or ▽ key takes you from View 1 or 2 to the Manual data storage or Transmit data menu. In addition to the automatic storage of alarm events, you can also store current data manually. Manual data storage stores data for the set Pre- and Post-alarm times just like in an alarm situation.

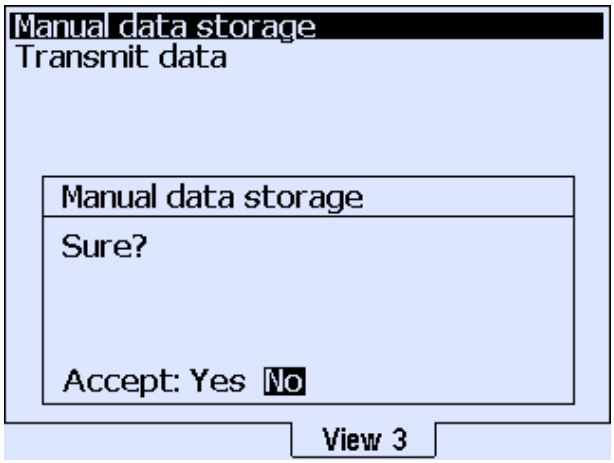


Fig. 72 View\ Manual data storage

The AUX socket is used to transmit data via a modem. The setting Since last transmission transfers only those new episodes stored since the last transfer, but no more than twenty.

The setting Last 20 episodes always transfers the last twenty episodes.

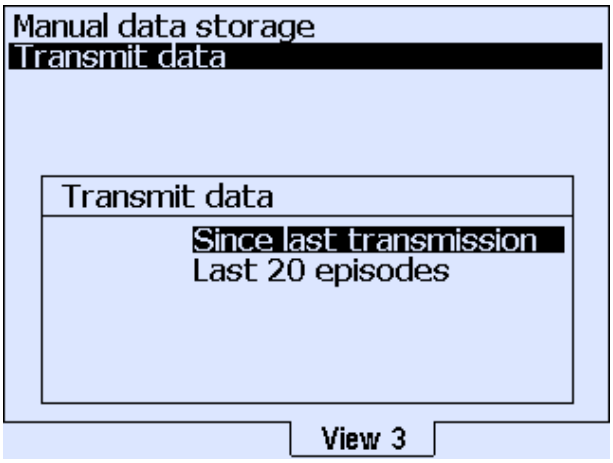


Fig. 73 View\ Transmit data

9.5.3 Summary of stored EVENTS

The symbols next to the name of each event appear on the EVENTS display in the columns for each physiological parameter following the time and duration of the event.

SpO_2 low	⬇	oxygen saturation lower than the set LOWER LIMIT
Silent SpO_2 low	(⬇)	measurement lower than the set silent alarm limit
SpO_2 high	⬆	oxygen saturation higher than the set UPPER LIMIT
Silent SpO_2 high	(⬆)	measurement higher than the set silent alarm limit
SpO_2 drop	⬇	when activated
Bradycardia	⬇	pulse rate lower than the set LOWER LIMIT
Silent bradycardia	(⬇)	pulse rate lower than the set silent LOWER LIMIT
Tachycardia	⬆	pulse rate higher than the set UPPER LIMIT
Silent tachycardia	(⬆)	pulse rate higher than the set silent UPPER LIMIT
Pulse rate drop	⬇	when activated
Pulse rate rise	⬆	when activated
Manual	M	manual storage (see "MANUAL DATA STORAGE or TRANSMIT DATA" on page 93)
Interval	I	INTERVAL storage (see "SYSTEM\ INTERVAL RECORDING" on page 90)

9.6 TREND storage

When an episode is highlighted, pressing <Enter> once displays the details, and pressing it a second time the trends.

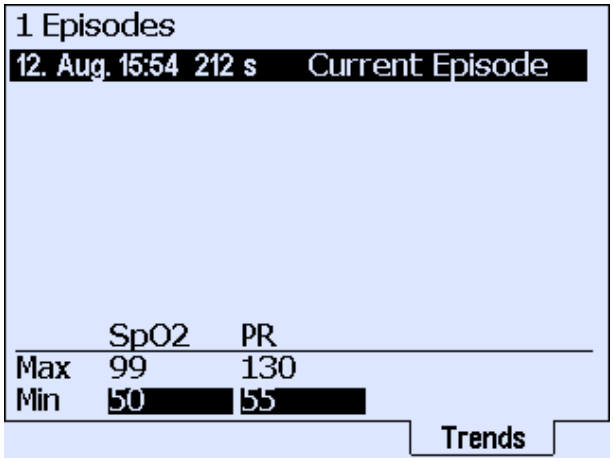


Fig. 74 List of the episodes stored in the trend memory

Over a max period of 72 hours the TREND memory stores all of the signals checked in the TREND column of the table on page 96.

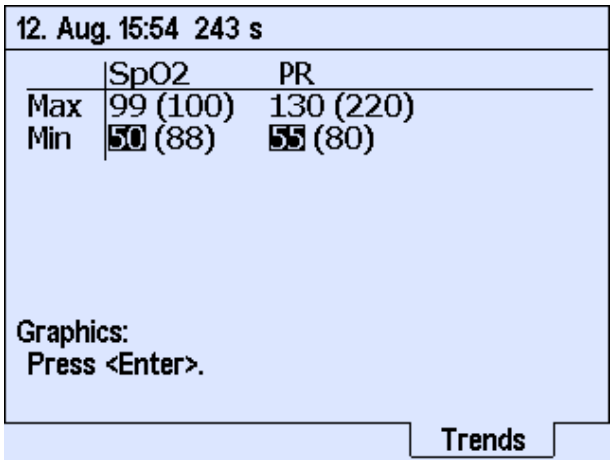


Fig. 75 Detailed information on a highlighted trend episode

9.7 LONG TERM storage over eight hours

Independent of alarm events, all signals are stored continuously for a maximum total time of eight hours for subsequent evaluation on a PC (full disclosure). After this period, the oldest data are overwritten.

9.8 PROTOCOL storage of operating and device data

The PROTOCOL memory registers e.g. when monitor settings are changed and when the device has been switched on and off. The following changes are stored in PROTOCOL memory:

- Monitor ON/OFF
- Admission of a new patient
- Changes to SETTINGS PROTECTION

The following data are stored with every change:

- Date and time of the change
- The current monitor settings

Protocol memory deletes the oldest data when more than 256 entries are stored.

9.9 Summary of stored signals and data

Data type	Sample rate [Hz]	ALARMS	LONG TERM	TREND
Current SpO_2	1	✔	✔	✔
Average SpO_2 for trend deviations	1	✔	✔	✔
Average SpO_2 over 1 min	0.2	✔	✔	✔
Average SpO_2 over 1 h	0.2	✔	✔	✔
Average SpO_2 over 6 h	0.2	✔	✔	✔
Average SpO_2 over 12 h	0.2	✔	✔	✔
Current pulse rate	1	✔	✔	✔
Average pulse rate for trend deviation	1	✔	✔	✔
Average pulse rate over 1 min	0.2	✔	✔	✔
Average pulse rate over 1 h	0.2	✔	✔	✔
Average pulse rate over 6 h	0.2	✔	✔	✔
Average pulse rate over 12 h	0.2	✔	✔	✔
Plethysmogram	64	✔	✔	
Perfusion	1	✔	✔	✔
Signal IQ	1	✔	✔	✔
Status graph	0.1	✔	✔	✔
AUX1	1	✔	✔	✔
AUX2	32	✔	✔	

9.10 Settings in the SpO_2 menu (Settings protection Off)

For these settings, Settings protection must be set to Off as explained under "System\ Settings protection On, Limited, Off" on page 72. The possible settings when Settings protection is set to Limited are explained in the section "SpO_2 menu – alarm settings (Settings protection Limited)" on page 75.

Factory settings are shown in bold type.

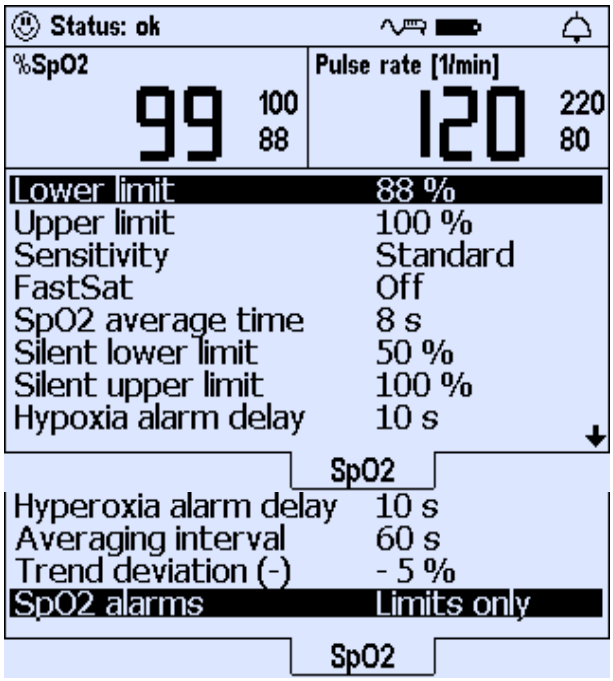


Fig. 76 Settings in the SpO_2 menu

Sensitivity ..... The Maximum setting is intended for patients with weak blood flow, but its higher sensitivity can hinder the correct detection of a loose SpO_2 sensor.
The Minimum setting is intended for patients with good blood flow. This setting utilizes the APOD™ (adaptive probe off detection) algorithm from Masimo Inc., a method that can correctly detect a loose sensor in almost all situations. On the other hand, patients with weak blood flow can trigger technical alarms more often. In most cases the factory setting **Standard** is recommended.

FastSAT™ ..... When FastSAT™ is **On**, this effectively takes a pulse-to-pulse measurement suitable for detecting sudden, short desaturations.

When the AVERAGE TIME is set to 4 or 6, FastSAT™ is automatically activated, even when it has been deactivated in this submenu.

AVERAGE TIME ..... 4, 6, **8**, 10, 12, 14, 16 seconds
Here you can view or set the period during which the SpO_2 module uses the sensor data to determine each SpO_2 and pulse rate value.

SILENT LOWER LIMIT (SpO_2) .. **50**, 51 ... 99, 100%
Lower alarm limit for the measured arterial oxygen saturation; when the measured value falls below this limit for longer than the set HYPOXIA ALARM DELAY, a silent alarm is stored.

SILENT UPPER LIMIT (SpO_2) .... 50, 51 ... 99, **100**%
As SILENT LOWER LIMIT (SpO_2), but with the HYPEROXIA ALARM DELAY.

HYPOXIA ALARM DELAY ..... 1, 2 ... **10** ... 19, 20 seconds
Time between when desaturation is detected (SpO_2 too low) and the corresponding alarm is triggered.

HYPEROXIA ALARM DELAY ..... 1, 2 ... **10** ... 19, 20 seconds
As above, but with the UPPER LIMIT for SpO_2.

AVERAGING INTERVAL ..... 10, 20 ... **60** ... 110, 120 seconds
The average SpO_2 measured over the set interval yields the reference value for calculating the TREND DEVIATION (-).

TREND DEVIATION (-) ..... -3, -4 ...**-10** ... -24, -25%
The current SpO_2 is compared every second with the average SpO_2 measured over the averaging interval. When the

current value falls below the average by more than the value set here and when SpO_2 ALARMS is set to LIMITS & TRENDS, an alarm is triggered.

SpO_2 ALARMS ..... When SpO_2 ALARMS is set to **LIMITS ONLY**, alarms are reported only when the measured values violate the set alarm limits. When SpO_2 ALARMS is set to LIMITS & TRENDS, alarms are reported when the measured values violate the set alarm limits AND when they deviate from the average SpO_2 measured over the set interval.

9.11 Settings in the PULSE RATE menu (SETTINGS PROTECTION OFF)

For this setting, Settings protection must be set to Off as explained under "System\ Settings protection On, Limited, Off" on page 72.

The possible settings when SETTINGS PROTECTION is set to LIMITED are explained in the section "PULSE RATE menu – alarm settings (Settings PROTECTION LIMITED)" on page 76.

Factory settings are shown in bold type.

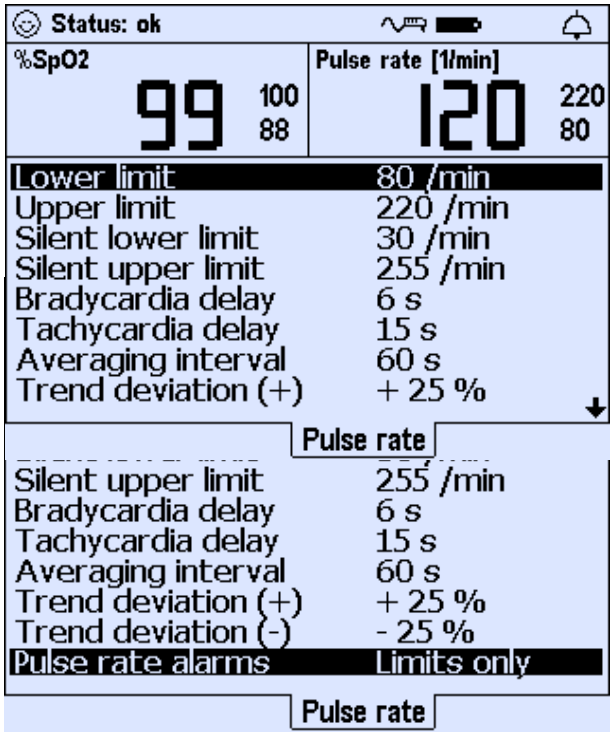


Fig. 77 Settings in the Pulse rate menu

SILENT LOWER LIMIT (PULSE) . **30**, 35 ... 50 ... 175, 180/min
Lower limit for the pulse rate; when the measured value falls below this limit for longer than the set BRADYCARDIA DELAY, a silent alarm is stored.

SILENT UPPER LIMIT (PULSE) .. 100, 105 ... **255**/min
See SILENT LOWER LIMIT.

BRADYCARDIA DELAY ..... 1, 2, 3, 4, 5, **6** ... 14, 15 seconds
Delay between when bradycardia is detected and the corresponding alarm is triggered.

TACHYCARDIA DELAY ..... 1, 2, 3, 4, 5 ... **15** ... 23, 24 seconds
See BRADYCARDIA DELAY, but for tachycardia.

AVERAGING INTERVAL ..... 10, 20 ... **60** ... 110, 120 seconds
The average pulse rate measured over the set interval yields the reference value for calculating TREND DEVIATION (+) and TREND DEVIATION (-).

TREND DEVIATION (+) 5, 10, 15, 20, **25**, 30, 35, 40, 45, 50%
The current pulse rate is compared with the average pulse rate measured over the averaging interval and an alarm is reported when the set percentage deviation is exceeded. This alarm is reported only when PULSE RATE ALARMS is set to LIMITS & TRENDS.

TREND DEVIATION (–) ..... See TREND DEVIATION (+), but the value falls below the set percentage deviation.

PULSE RATE ALARMS ..... – When PULSE RATE ALARMS is set to LIMITS ONLY, acoustic alarms are reported when the measured values violate the set alarm limits.

– When PULSE RATE ALARMS is set to LIMITS & TRENDS, acoustic alarms are reported when the measured values violate the set alarm limits AND when there is a positive or negative deviation from the average pulse rate measured over the set interval.

10 Algorithms and measuring principles

Knowledge of the following calculation bases is essential if VitaGuard® is to be properly configured.

10.1 Alarm condition and report delays

As prescribed in the standard IEC 60601-1-8 “General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems”, this section allows the doctor to become familiar with the set and inherent delays for the correct configuration of the alarm limits and monitoring parameters.

- The alarm *condition* delay is the time from the occurrence of a triggering event on the patient or in the monitor to the decision by the alarm system to confirm an alarm condition.
- The alarm *report* delay is the time between when an alarm condition is detected and when it is reported.
- The alarm *condition* delay and the alarm *report* delay are added to yield the ALARM SYSTEM delay.

The algorithms listed here are based on worst credible cases, i.e. the calculations always return the maximum possible delays.

An alarm *condition* delay as defined in the standard does not occur when oxygen saturation is monitored. Please observe though the information on alarm *report* delays below.

10.2 Alarm report delays

The alarm report delays for bradycardia, tachycardia, hypoxia, and hyperoxia can be set within certain limits.

$TA_{(max)}$ for bradycardia: ..... set BRADYCARDIA DELAY + 2 s

$TA_{(max)}$ for tachycardia: ..... set TACHYCARDIA DELAY + 2 s

$TA_{(max)}$ for hypoxia: ..... set HYPOXIA ALARM DELAY + 2 s

$TA_{(max)}$ für hyperoxia: ..... set HYPEROXIA ALARM DELAY + 2 s

The purpose of these alarm report delays is to prevent alarms from being reported every time the alarm limits are violated for short times only.

In other words, the maximum alarm report delay corresponds to the maximum set delay. The monitor outputs measurements e.g. to the display every second. The technology's contribution to the total alarm report delay is specified as maximum two seconds overall.

10.3 Measuring principle for the SpO_2 monitor

The pulse oximeter with Masimo SET® (SET = Signal Extraction Technology®) is based on the following three principles.

1 Oxyhemoglobin (oxygenated hemoglobin) and deoxyhemoglobin (unoxygenated hemoglobin) differ in their absorption of red and infrared light (spectrophotometry).

2 A heartbeat gives rise to a pulse wave that during its cycle changes the volume of arterial blood and therefore its light absorption at the monitoring site (plethysmography).

3 In particular movements also give rise to blood flows that resemble pulse waves and generate interference signals.

Like conventional pulse oximeters, SET® oximeters determine oxygen saturation by directing red and infrared light through tissue and measuring the absorption of light by the blood flow. Light-emitting diodes (LEDs) serve as light sources and a photodiode as the receiver attached opposite.

Conventional pulse oximetry assumes that all pulsations in the light absorption are caused by the arterial pulse cycle. For this to work, the venous blood in the sensor area must flow completely and therefore constantly through the capillary bed. Conventional pulse oximetry then calculates the ratio of the pulsatile to the mean absorption for both wavelengths (660 nm and 940 nm).

The quotient of the two signals is then formed as follows:

R = S(660)/S(940)

The result R is used to read the corresponding SpO_2 value out of an empirically calibrated table mapped in the oximeter software. These tables were drawn up in trials with volunteers who underwent temporary induced hypoxia. During these trials a conventional pulse oximeter was used for the measurements; at the same time, arterial blood was extracted and examined for its oxygen content.

Unlike conventional pulse oximeters, Masimo SET® pulse oximeters assume that not only the arterial, also the venous blood flow varies greatly. Changes to venous light absorption are regarded as a significant source of interference to the pulse signal. The SpO_2 module separates the signals for both wavelengths S(660) and S(940) into an arterial signal S and a noise component N that are then used to calculate the ratio R:

S(660) = S1 + N1

S(940) = S2 + N2

R = (S1 + N1) / (S2 + N2)

N1 and N2 are the noise components generated by venous blood.

The DST™ method (discrete saturation transform) isolates and therefore compensates for venous interference components.

The SET® software goes through all the possible values for R (corresponding to SpO_2 between 1 and 100%) and calculates the associated interference components. An adaptive noise canceller, or ANC, then takes this value N'(R) to calculate the amplitude of the noise energy, or the so-called output power of the ANC. The result is a DST™ plot (Fig. 78) that exhibits at least the arterial peak. This peak demonstrates the particularly effective noise suppression for the affected SpO_2 value when a precisely defined source of signal fluctuations, the arterial pulse cycle, has been identified. Other, also higher peaks can occur during venous fluctuations. Venous blood is saturated less with oxygen, so the peak with the maximum SpO_2 value (in the right half of the graph) always corresponds to the arterial oxygen saturation. In Fig. 78 the right peak corresponds to an SpO_2 of 97%. The DST calculation is repeated every two seconds on the latest raw data over the preceding four seconds.

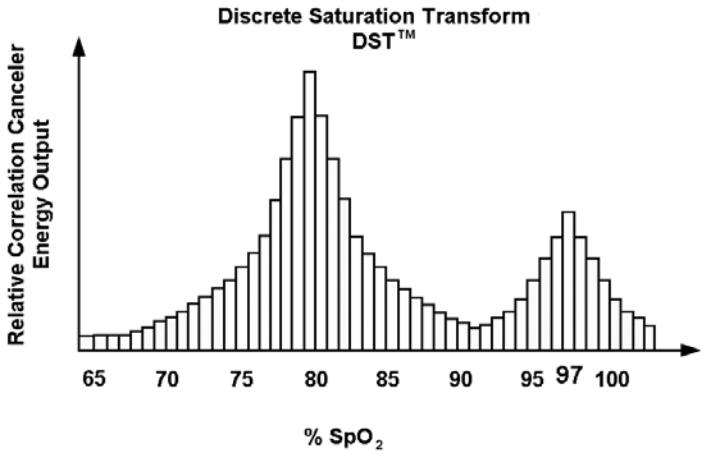


Fig. 78 DST™ plot: relative noise cancellation as a function of SpO_2

The peak at 80% is caused by venous blood and would, with the conventional method, have completely corrupted the measurement for a false desaturation.

The PERFUSION index (a percentage value) displayed on the monitor is calculated from the electric signal of infrared light captured by the sensor's photodiode. This signal has a constant and a varying component depending on whether the infrared light is absorbed by bone, connective tissue, skin, or pulsatile blood.

The ratio of constant to variable signal component is used to calculate the perfusion index, a value between 0 and 20%. When the PERFUSION index is very small, SpO_2 and the pulse rate are no longer monitored. When the SENSITIVITY in the SpO_2 menu is set to MAXI-

MUM, the cut-off limit is 0.02%; when set to STANDARD, the limit varies from 0.5 to 0.02% depending on the signal quality.

Further information about FastSat™, APOD™ (adaptive probe off detection), perfusion index, and signal IQ can be found in the white papers at www.masimo.com.

11 Evaluating stored data on a PC

getemed AG has developed the Windows®-based software VitaWin® for evaluating the recorded monitoring data. This software is provided only to doctors and authorized dealers who are or supply VitaGuard® users.

The stored data can be downloaded through the USB (universal serial bus) port to a PC where they can be stored, viewed, and evaluated.

VitaWin® presents each alarm's context based on the signals Respiration, Respiration rate, Basal impedance, ECG, Heart rate, Pulse rate, SpO_2, Plethysmogramme, Signal IQ, and Perfusion.

VitaWin® also provides functions for drawing up reports and assessing the patient's monitored data.

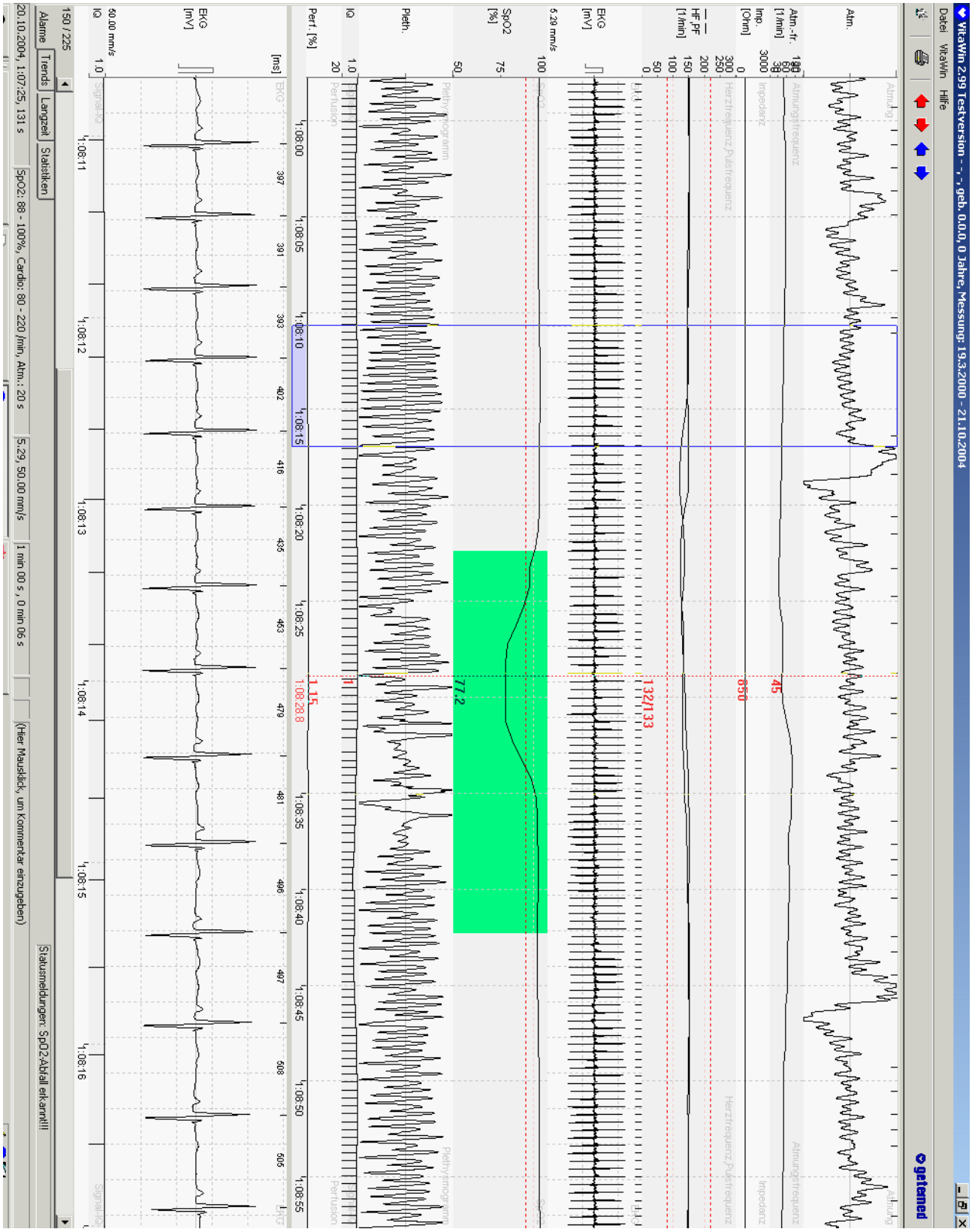


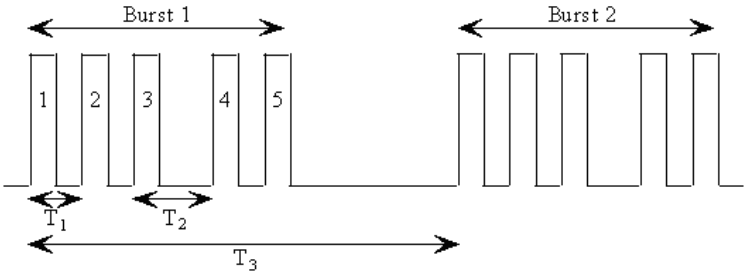
Fig. 79 VitaWin®\ register "Events in graph form"

12 Specifications

12.1 General

Weight	approx. 650 g with non-rechargeable batteries approx. 700 g with rechargeable block battery
Dimensions	13.5 x 20.3 x 4.5 cm
Non-rechargeable batteries	4 x 1.5 V (type LR6, AA), alkaline
Chargeable block battery	NiMH/4.8 V/2000 mAh
Charging time	6 hours
Battery life	e.g. VARTA UNIVERSAL ALKALINE: min 8 hours
Keys	6 membrane keys
Battery change	displayed message
Depleted battery	acoustic alarm
Power consumption	< 10 W
Power adapter	NA3000-2 power adapter Manufacturer: FRIWO Gerätebau GmbH Type: FW 7555MM / 09 Output: 9 V, 1500 mA, DC Input: 100–240 V, 50–60 Hz, 400 mA, AC Ingress of protection: IP 40

Characteristics of acoustic alarm signals ..... acoustic signals for higher-priority alarms consist of two acoustic sequences of five tones each:



Pulse duration	-	155 ms ± 5 ms
Rise and fall time	-	17 ms ± 3 ms
Time between start of pulse 1 and start of pulse 2	T_1	215 ms ± 20 ms
Time between start of pulse 2 and start of pulse 3	T_1	215 ms ± 20 ms
Time between start of pulse 3 and start of pulse 4	T_2	440 ms ± 20 ms
Time between start of pulse 4 and start of pulse 5	T_1	215 ms ± 20 ms
Time between start of burst 1 and start of burst 2	T_3	2 s ± 0.1 s
Repeat time for the whole sequence	-	10 s ± 0.2 s

acoustic signals for medium-priority alarms consist of three-pulse bursts:

Pulse duration	185 ms ± 5 ms
Rise and fall time	17 ms ± 3 ms
Time between start of pulse 1 and start of pulse 2	375 ms ± 20 ms
Time between start of pulse 2 and start of pulse 3	375 ms ± 20 ms
Repeat time for the whole sequence	5.2 s ± 0.2 s

Characteristics of system monitoring signals	pulsating tone of 4 kHz and 1 Hz pulse rate from the sound aperture between the sockets
Displays	LEDs and LCD graphic display with 240 x 360 dots
Display refresh rate	1 Hz
Expected service life (as per DIN EN ISO 18778)	min seven years
Inspection and servicing intervals	getemed AG prescribes safety checks, function checks, and servicing every eighteen months. The next appointment is specified on a label in the battery compartment.

12.2 SpO_2 and pulse rate monitor

SpO_2 display range	1–100 %
Pulse rate range	25–240/min
Perfusion index	0.02 %–20 %
* SpO_2 accuracy (calibrated range) for all age groups	– when SpO_2 > 70 %, ±3 digits when patient moving or still – when SpO_2 < 70 %, unspecified
* Pulse rate accuracy for all age groups	± 3/min when patient still ± 5/min when patient moving
SpO_2 resolution	1 %

Pulse rate resolution	1/min
Heat emission	max 50 mW (at the LNOP® sensor)
Accuracy with weak perfusion (i.e. pulse amplitude > 0.02 % and transmission > 5 %)	SpO_2 ±2 digits pulse rate ±3 digits

* The specified tolerances correspond to a standard deviation of ± 1. This means that within these tolerances, the pulse rate and %SpO_2 can be determined for 68% of the population.

12.3 Intervals for calculating average values in the INFO mask

Minute values for SpO_2, PR	1 s
Hour values for SpO_2, PR	30 s
Six-hour values for SpO_2, PR	300 s
Twelve-hour values for SpO_2, PR	300 s

12.4 Memory

Storage medium	64 MB compact flash memory card (memory extendable on request)
Nr. of episodes	max 200 episodes of two minutes each
Trend	max 72 hours
Long term (full disclosure) ...	max 8 hours

12.5 Ports

USB	mini USB port
AUX	– modem port (RS232) – socket for a nurse call system – socket for an external alarm unit – socket for two analog inputs from 0 to 2.5 V at 1 or 32 Hz

12.6 Miscellaneous

German “Hilfsmittel-nummer”	21.24.02.5005
Calibrating time after activation	< 60 s
MPG device class	IIb
Device protection class	II as per DIN EN 60601-1
Type of application part	BF
Ingress protection	IP 21
Operating temperature	5–40 °C
Operating humidity	5–95%, non-condensing
Ambient pressure, height above sea level	1060–500 mbar, -304 to +5486 m
*Storage and transport conditions	–40 to +70 °C; humidity 15–95%, non-condensing
EMC classification	CISPR 11, class B

12.7 Selection of applied standards

IEC 601-1	Medical electrical equipment – Part 1: General requirements for safety, incl. A 13
IEC 60601-1-1	Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
IEC 62A/422/CDV:2003	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
IEC 60601-1-8	Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
DIN EN 60601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunctional patient monitoring equipment
DIN EN 865	Pulse oximeters – Particular requirements
ISO 18778	Infant Monitors – Particular requirements

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